UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION	)	**MDL No. 2272**
	)	**Master Docket No. 11 C 5468**
KATHY L. BATTY,	)	
Plaintiff,	)	
v.	)	**No. 12 C 6279**
ZIMMER, INC., ZIMMER HOLDINGS, INC., and ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS, INC.,	)	**Judge Rebecca R. Pallmeyer**
Defendants.	)	

MEMORANDUM OPINION AND ORDER

In courts throughout the country, individuals who underwent total knee replacement surgeries have sued Defendants, Zimmer Inc. and its affiliates (collectively, "Defendant" or "Zimmer"), manufacturers of the Zimmer NexGen Flex Knee system. Plaintiffs allege that the femoral and tibial components of that system are prone to premature loosening, resulting in pain and loss of movement, and, in some cases, necessitating revision surgery. On August 8, 2011, the United States Judicial Panel on Multidistrict Litigation issued a transfer order consolidating Plaintiffs' cases in this court for pretrial proceedings. The parties have selected three bellwether cases to proceed to trial, the first of which is brought by Plaintiff Kathy Batty and her husband, Thomas Batty. Ms. Batty claims that Zimmer is strictly liable for the design defect in its NexGen Flex knee, that Zimmer negligently designed the knee, and that Zimmer negligently failed to warn patients and physicians about the risks of loosening. Ms. Batty seeks compensatory and punitive damages. Mr. Batty seeks damages for loss of consortium.

In support of her claims, Ms. Batty offers the opinions and testimony of several experts, which Zimmer moves to exclude under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). In a separate motion, Zimmer urges the court to exclude all expert testimony regarding loosening of the tibial component of the NexGen Knee system [1309]. Zimmer contends that such testimony is speculative and scientifically unreliable, because it contradicts findings from dozens of empirical studies supporting Zimmer's contention that there is no increased rate of tibial loosening with the NexGen Flex products. Zimmer has also submitted two separate motions for summary judgment [1306] [1317], seeking judgment as a matter of law on each of Ms. Batty's claims.

In this opinion, the court addresses Zimmer's *Daubert* challenges to Plaintiff's experts Dr. Thomas Brown [1298] and Dr. Joseph Fetto [1300], and to testimony of any expert regarding tibial loosening [1309]. As explained below, the court denies Zimmer's motion to exclude Dr. Brown's testimony: Zimmer does not challenge his qualifications, and the court concludes that his opinions are reliable and relevant. Because the court concludes that Dr. Brown's testimony regarding tibial loosening is admissible, Zimmer's motion to exclude all testimony, by any expert, concerning tibial loosening is denied. The court will, therefore, separately evaluate the reliability and methodology of Plaintiff's remaining expert testimony on tibial loosening. Having done so with respect to Dr. Fetto, the court grants Zimmer's motion to exclude his opinions in part: The court concludes that Dr. Fetto is qualified to opine on biomechanics, but that his opinions regarding (a) the risks of tibial and femoral component loosening; (b) the adequacy of Zimmer's warnings; and (c) the adequacy of Zimmer's pre-market testing are not based on a reliable methodology. His rebuttal report to Zimmer's expert, Dr. D'Lima, is however, sufficiently

grounded in reliable scientific literature and will be admitted in the event that the court determines that Dr. D'Lima's opinions are admissible.[1]

This opinion addresses only those portions of Zimmer's summary judgment motions that challenge Ms. Batty's design defect claims and Mr. Batty's claim for loss of consortium. For now, the court reserves judgment on Zimmer's remaining summary judgment arguments, including its challenges to Ms. Batty's failure to warn claim and to her request for punitive damages. Zimmer urges that it is entitled to judgment on Ms. Batty's "non-negligence-based product liability claims" because Pennsylvania law does not recognize such claims. Zimmer also contends that Ms. Batty lacks evidence of causation and defect and that Zimmer is entitled to summary judgment on her negligent design defect claim as well. The court agrees with Zimmer that the Supreme Court of Pennsylvania, if presented with the issue, would dismiss Plaintiff's strict liability claim. The motion for summary judgment on multiple grounds [1306] is granted with respect to that claim, but denied with respect to the claim of negligence: Material disputes of fact remain regarding whether Zimmer negligently tested and designed the NexGen Flex implant, resulting in Ms. Batty's tibial and femoral loosening. Zimmer's separate motion for summary judgment on Ms. Batty's claims of femoral loosening due to high flexion [1317] is likewise denied.

BACKGROUND

Plaintiff Kathy Batty suffers from degenerative joint disease in both knees. (Operative Reports, Ex. Q to Zimmer's SOF [1330-17].) In April 2009, her treating physician, Dr. Alan Klein, performed total knee replacements on both of Ms. Batty's knees: The right knee surgery

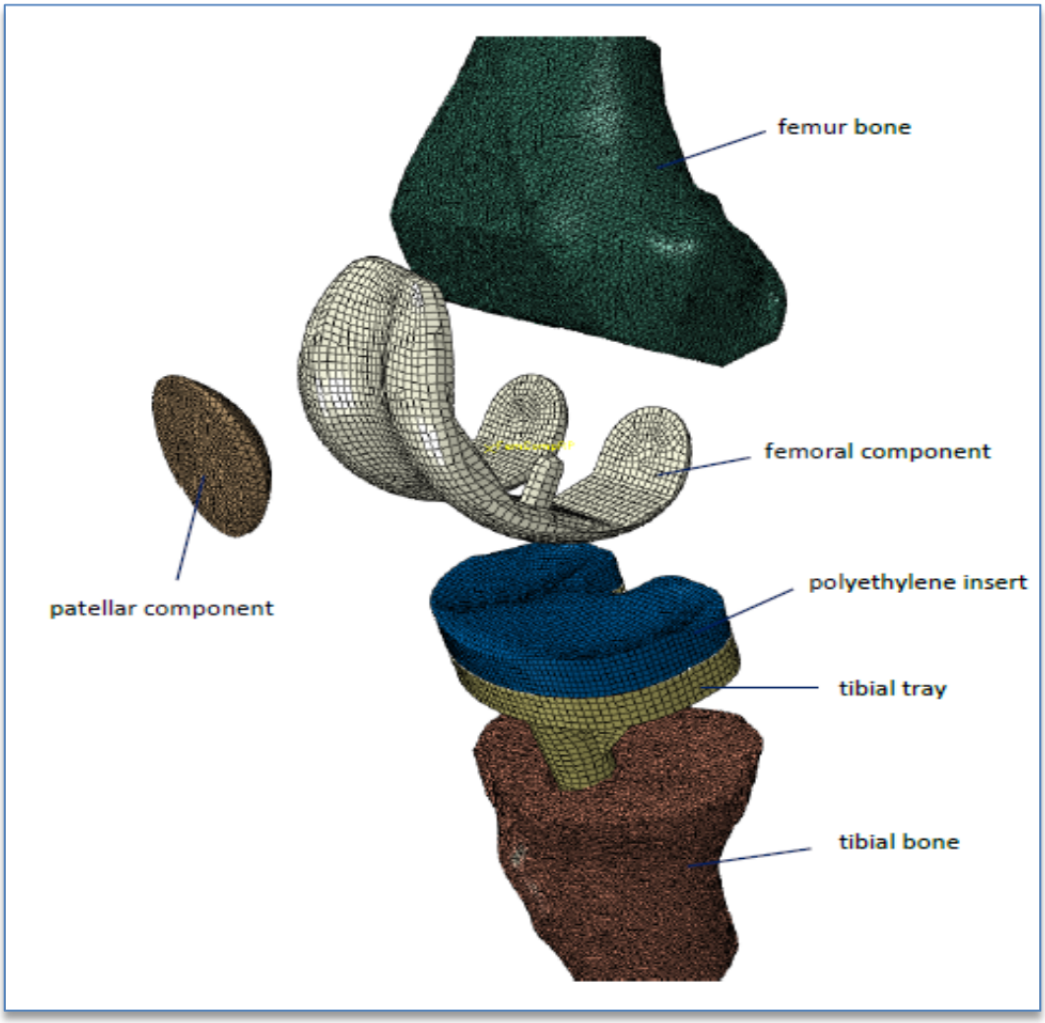
[1] Dr. D'Lima created a computer model of the NexGen Flex implants to predict the amount of stress and force the implant experiences and to predict how the implant would respond to those forces. Based on the model, Dr. D'Lima concluded that the forces acting on polyethylene surface of the Flex "were comparable," or lower than the Standard; that plastic deformation of the polyethylene surface was lower for the Flex; and that there was insufficient movement between the bone and implant to cause loosening. (Report of Dr. Darryl D'Lima, Ex. 1 to Pl.'s Mem. in Supp. of Mot. to Strike Dr. D'Lima [1313-1], 5–7.)

took place on April 14, 2009, and the left knee two weeks later, on April 28. (Pl.'s Local R. 56.1(b)(3) Resp. to Zimmer SOF [1461], hereinafter "Pl.'s Resp. to SOF," ¶ 41.) Dr. Klein implanted a NexGen LPS-Flex Gender Solutions femoral component and a NexGen Stemmed Tibial Component Option in each knee. (Zimmer's Stmt. of Undisputed Mat. Facts in Supp. of Summ. J. [1330], hereinafter "Zimmer SOF," ¶ 41; Pl.'s Resp. to SOF ¶ 41.)

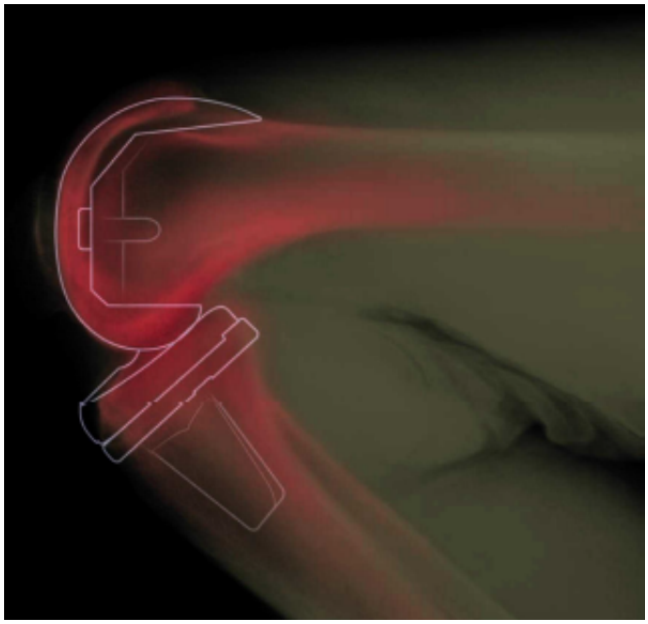
A total knee implant replaces the top part of the shin bone—the tibia—and the bottom part of the thigh bone—the femur. When designing the LPS Flex implants, Zimmer made alterations to an existing product, the NexGen Complete Knee Solution (also referred to as the "Standard" knee), that it believed would enable patients to achieve higher flexion—that is, a greater bend of the knee. The Standard knee only permitted flexion up to 130 degrees, but as Zimmer's brochure explains, "[t]he LPS-Flex Knee represents a new and distinct choice from the wide selection of NexGen Knees. . . . The LPS-Flex femoral component extends the NexGen Complete Knee Solution to patients capable of up to 155 degrees of active flexion." (Zimmer Brochure for the LPS-Flex, Ex. B to Batty's Mem. of Law in Resp. to Partial MSJ Mot. [1464-2], hereinafter "Brochure," Z05608001.) The Flex knee was intended to allow patients to engage in activities requiring greater flexion, such as squatting and kneeling, as depicted in the brochure. (*See* Brochure at Z05607997–98.) Ms. Batty understood that she was getting a knee for "active people," and Dr. Klein explained he understood that the "whole idea" of the NexGen Flex knees was that they "were designed for people who wanted to perform high-flexion activities." (Pl.'s Resp. to SOF ¶ 42; Klein Dep. at 176:14–23.)

The tibial component of a knee implant consists of a metal tray that sits on top of the tibia and a stem that extends downward into the tibia. The metal tray can be cemented to the bone. Alternatively, the tibial component will bond directly to the bone without the use of cement, as the bone grows into the implant through a process called "osseointegration." Dr. Klein chose to cement Ms. Batty's implant and used one pack of cement for both the tibial component and the femoral components. (*See* Batty Operative Reports, Ex. Q to Zimmer SOF

[1330-17], 1.) On top of the flat metal tray of the tibial component is a polyethylene surface ("poly") that serves as the point of contact for the femoral component:



(Construction and Validation of a Model of Knee Flexion, Ex. D to Report of Daryl D'Lima, Ex. E Zimmer Fetto Mem. [1301-5], 3.)



(Brochure at Z05607996.) The poly comes in different sizes representing its thickness. Dr. Klein tested both the 12 millimeter and the 14 millimeter poly and decided to use the 14 millimeter because he believed it would enable Ms. Batty to achieve better stability. (Batty Operative Reports at 1.)

Ms. Batty began physical therapy almost immediately after her first surgery. She testified that the day following surgery, she walked down the hall outside her hospital room. (Dep. of Kathy Batty, Ex. 13 to P. Resp. to Zimmer SOF [1462-13], hereinafter "Batty Dep.," 173:7–174:10.) She also practiced climbing stairs with the physical therapist in the hospital. (*Id.* at 175:6–176:17.) She continued physical therapy after her discharge from the hospital and remained in formal physical therapy through July 2009. (Decl. of Kathy Batty, Ex. 22 to P. Resp. to Zimmer SOF [1462-22], hereinafter "Batty Decl.," ¶ 2.) While in physical therapy, on July 17, 2009, Ms. Batty's highest recorded degree of flexion was documented as 120–121 degrees in her right knee and 128 degrees in her left knee. (Zimmer SOF ¶ 42; Physical Therapy Notes, Ex. R to Zimmer SOF [1330-18], hereinafter "PT Notes.") Though the physical therapy notes do not state what methodology was used to measure her flexion, she testified that the physical therapists attached a strap to her leg, and "would push" her knee "to bend it more

so they could get a better number." (Batty Dep. at 199:5–6, 200:13–17.) Dr. Klein also measured Ms. Batty's flexion in his office, beginning shortly after surgery, and through 2010 during follow-up visits. He testified that the highest degree of flexion he recorded was 120 degrees in both knees on July 8, 2009, though later he testified that in November 2010 he recorded her left knee having 125 degrees of flexion. (Dep. of Alan Klein, Ex. T to Zimmer SOF [1330-20], hereinafter "Klein Dep.," 78:13–79:8; 149:3–12.) Dr. Klein did not make a record of his methodology for measuring Ms. Batty's flexion, but he testified that when he measured patients "on the exam table" he did "not really push[] . . . that hard," and he expected that if a patient had his or her "whole body weight on their knee, they could achieve greater flexion than we normally do when we measure them." (Klein Dep. at 77:15–19.) He expected that the increased flexion would be "[w]ithin a couple of degrees [of what he observed in his examination], but . . . the body weight force is going to create a little more flexion than I would [by] just passively moving the knee." (*Id.* at 78:9–12.)

After her formal physical therapy ended, Ms. Batty continued informal physical therapy on her own. (Batty Decl. ¶ 3.) She exercised using a "Total Gym," roughly four times a week, including roughly 60 squats: 30 using both legs, plus 15 squats on her right leg alone, and 15 on her left alone. (*See Id*.) Ms. Batty acknowledged that the squats she performed were not deep enough to cause her calf and thigh to touch, and in fact "[t]hey haven't touched in years." (Batty Dep. at 196:14.) She stated in her declaration that she "believe[s] the amount of bend [she] got doing the squats was more than [she] got in the office with Dr. Klein when he would gently bend [her] knee." (Batty Decl. ¶ 3.) When asked in her deposition whether she was "ever able, outside of physical therapy to bend [her] knee more than they bent it in physical therapy," she initially responded "[n]o." (Batty Dep. at 199:25–200:3.) She went on, however, to explain that she was uncertain whether she bent the knee more outside of therapy because she "did not have someone else measuring it." (*Id*. at 200:4–8, 200:18–24.)

As of October 2009, Ms. Batty was back at work full-time, as a custodian for the U.S. Postal Service, with no physical restrictions. (Pl.'s Stmt. of Additional Facts [1461], hereinafter "Pl.'s SAF" ¶ 12; Batty Decl. ¶ 4.) Her job responsibilities included maintaining a large flower bed; she planted some 200 flowers and then kept up the flower bed by weeding regularly. (Batty Decl. ¶ 4.) This work required Ms. Batty to kneel and squat. It "felt weird" to kneel with the implants, she noted, so she "would kneel some and squat some" to do her work. (*Id.*) Ms. Batty's job also required her to climb ladders and wash baseboards. (*Id.*)

By July 2010, Ms. Batty began to notice pain in both knees. (Fetto Report on Kathy Batty, Ex. L to Ronca Decl. [1464-12], hereinafter "Fetto Batty Rep.," 2.) Dr. Klein saw Ms. Batty again in November of 2010. (Klein Dep. at 148:18–25.) At that visit, Ms. Batty reported that her left knee was doing pretty well, but her right knee bothered her, "especially with activities." (*Id*. at 149:3–6.) She noticed stiffness and observed that she could not bend her right knee as far as the left. (*Id*. at 149:6–8.) X-rays taken at that visit showed "some radiolucencies[2] around her right tibial tray" that may have been "a little bit enlarged from" the x-rays taken immediately after surgery. (*Id*. at 149:15–19.) Based on those x-rays, Dr. Klein was concerned that she was developing some loosening and ordered a bone scan. (*Id*. at 148:18–19.) The results of the bone scan suggested that loosening and infection were likely, but the blood tests Dr. Klein ordered next showed no signs of infection. (*Id*. at 149:8–16; 20–23.) Once he determined that her knees were loose but not infected, he sent her to Dr. Sewecke, another doctor in his practice, for a second opinion. (*Id*. at 149:8–16.) In Ms. Batty's February 8, 2011

[2] A radiolucency is "a radiographic finding. It's a description of a change in density surrounding the implant." (Fetto Dep. at 147:13–16.) Dr. Brown explains that radiolucencies "are features of darkening in x-rays, in what otherwise should be bright-appearing bony regions. These local darkenings are due to the bone being less dense − or even absent − at these locations. Substantial radiolucencies adjacent to implants are indicative of reduced or even totally absent bony support, and they correlate with implant loosening or impending implant loosening, especially when the radiolucencies are progressive with time." (Thomas Brown Exp. Rep. [1454-5], hereinafter "Brown Rep.," 8, n.3.)

medical record, Dr. Sewecke documented "evidence of radiolucency at the bilateral tibial components." (*Id*. at 75:9–12.) He also observed that the tibial components appeared to be in varus alignment—that is, the tibial component was not aligned parallel to the tibial bone, but was tilted outward.[3] (*Id*. at 75:20–76:1.)

On March 1, 2011, Dr. Klein referred Ms. Batty to Dr. Lawrence Crossett, another orthopedic surgeon. Dr. Crossett concluded that her x-rays showed tibial loosening in both knees, and that revision surgeries were necessary. (Dep. of Lawrence Crossett, Ex. C to Zimmer's Reply in Supp. of Mot. for Summ. J. [1488-3], hereinafter "Crossett Dep.," 130:2–3.) He was unsure whether the femoral components were loose or rotated, but decided to revise the femoral components as well in order to "take full control and responsibility for the implants." (*Id*. at 152:33–16.) Dr. Crossett performed the revision surgeries on April 18, 2011 (right knee) and May 11, 2011 (left knee), implanting a DePuy LCS revision system in each of Ms. Batty's knees. He described the indication for both surgeries as bilateral tibial loosening, and his notes following the surgery confirm that each of Ms. Batty's tibial components was loose. (Revision Reports, Ex. 25 to Decl. of Ronca in Supp. of Resp. to Zimmer Mot. for Partial Summ. J. [1462-25].) In the notes following the left-knee surgery, for example, he referred to the tibial component as "loose" and noted that he was able to remove it "rather easily." Evidence of femoral loosening was less pronounced: To remove the left femoral component, Dr. Crossett used a "small oscillating saw" and "small osteotomes" to "interrupt[]" the interface between the cement and metal of the component. (*Id.*) In the pre-operative report for Ms. Batty's right knee, Dr. Crossett observed that she had "some looseness about the femur, though [he was] not

[3] Dr. Sewecke used the terms "varus" and "valgus" to describe the angle between the tibial component and the tibia bone. These same terms are also used to describe the overall alignment of the knee, that is, the alignment of the femur in relation to the tibia. In this latter context, varus refers to a bow-legged misalignment and valgus refers to a knock-knee misalignment. (*See* Klein Dep. at 63:8–12.)

convinced they are loose." (*Id.*) Nonetheless, he was "concerned about their long-term durability" and removed them using "an oscillating saw and mallet." (*Id.*)

Dr. Joseph Fetto, one of Plaintiff's retained experts, reviewed Ms. Batty's medical records as part of this litigation. According to Dr. Fetto's review, the x-rays taken immediately after the initial surgeries "showed good fixation, good cement, angle, and appropriate alignment." (Fetto Batty Rep. at 3) In contrast, x-rays taken in November 2010 revealed "what appeared to be lucencies beneath the tibial tray" and "resorption of the bone at the distal femoral bone-prosthesis interface, indicative of additional evidence of mechanical failure of the implants." (*Id.* at 2.) He concluded that "there was a progressive lucency about both the tibial and femoral components, which worsened" over time. (*Id.* at 3.)

In July 2012**,** Ms. Batty filed this products liability suit, alleging that Zimmer's negligence in testing and designing the NexGen Flex knee increased the risk of both the femoral and tibial components prematurely loosening. She maintains that even if Zimmer was not negligent in its design and testing of the Flex knee, it is strictly liable for the injuries the knee caused. Further, she argues that Zimmer negligently failed to warn of the increased risks of loosening and requests compensatory and punitive damages for her injuries.[4] Ms. Batty has presented the testimony of Dr. Thomas Brown and Dr. Joseph Fetto, who opine that the design of the Flex, when used at high degrees of flexion, increases the pressure on the implant, causing both the tibial and femoral components to loosen.[5] As noted, Zimmer seeks an order excluding their

[4] Ms. Batty initially presented claims for unjust enrichment, breach of express and implied warranties, negligent manufacturing defect, and violations of Pennsylvania's Uniform Trade Practices and Consumer Protection Laws. Plaintiff now represents that she "will not pursue at trial any manufacturing defect, breach of express warranty, unjust enrichment, or Pennsylvania Consumer Protection claims and as such, those claims are withdrawn." (Pl. Resp. to Mult. Grounds Mem. [1465], hereinafter "Mult. Grounds Resp.," 1.) She is, therefore, only pursuing her negligent and strict liability design defect claims and her failure to warn claim.

[5] The parties have presented the testimony of several other experts, as well. Challenges to the admissibility of that evidence will be addressed in subsequent opinions.

expert testimony. Dr. Brown, a well-qualified expert in biomechanical engineering, has identified several signature design features that, in his view, increase the risk of implant loosening when the design is used in high flexion, and could have been detected with proper testing. Dr. Fetto, an orthopedic surgeon, similarly opines that the design of the NexGen Flex increases the risk of aseptic loosening and that Zimmer's testing was inadequate. Moreover, in Dr. Fetto's view, Zimmer failed to provide adequate warnings about the risk of loosening in high flexion. Finally, Dr. Fetto offers his medical opinions regarding Ms. Batty's specific treatment, which Zimmer has not challenged.

In addition to its challenges to Plaintiff's experts, Zimmer brings two motions for summary judgment. First, Zimmer moves for summary judgment on multiple grounds [1306], arguing that Ms. Batty's strict liability claim is not cognizable under Pennsylvania law and that Ms. Batty has not identified evidence to support a claim of negligent design defect that rests on a theory of tibial loosening.[6] Zimmer incorporates its motion to exclude any expert testimony regarding tibial loosening [1309] as unreliable under Rule 702 and *Daubert* and asserts that if the court grants that motion, it is entitled to summary judgment on all of Plaintiff's design defect claims that are tethered to tibial loosening theories.

Zimmer's second motion for summary judgment [1317] asks the court to prohibit Ms. Batty from presenting certain theories of defect related to femoral loosening.[7] Zimmer maintains that Ms. Batty only achieved a maximum of 128 degrees of flexion, and only in one knee.

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[6] In its motion for summary judgment on multiple grounds, Zimmer also contends it is entitled to summary judgment on Ms. Batty's failure to warn claim and her request for punitive damages. The court addresses the strict liability, negligent design defect, and loss of consortium claims in this opinion and reserves judgment on the remaining issues.

[7] Zimmer makes overlapping arguments regarding Ms. Batty's lack of evidence to show femoral loosening in its motion for summary judgment on multiple grounds. (*See* Zimmer Mem. in Supp. of Mot. for Sum. Judg. on Mult. Grounds [1308], hereinafter "Mult. Grounds Mem.," 6–7.) As these motions both assert that Ms. Batty has failed to present evidence to support a theory of femoral loosening, the court addresses those arguments together.

Based on that level of flexion, Zimmer continues, the only functional difference between the Flex model at issue in this litigation and Zimmer's Standard knee implant is that the Flex requires the surgeon to cut an additional two millimeters of bone from the femur. With respect to her femoral loosening theories, Zimmer urges, Ms. Batty should be limited to evidence of harm resulting from the additional two millimeters of bone cut. But the opinions offered by Dr. Brown and Dr. Fetto concerning the two millimeter bone loss are not methodologically sound, Zimmer contends, meaning that Ms. Batty has no evidence of a design defect that could have caused femoral loosening in her case.

As explained more fully below, the court finds that Dr. Brown's opinions are reliable and relevant and denies Zimmer's motion [1298] to exclude his testimony. That testimony is sufficient to support theories of tibial loosening and femoral loosening based on the required additional two millimeter bone cut. Zimmer's motion to exclude all expert testimony of tibial loosening [1309] is, accordingly, denied. Dr. Fetto, while qualified through his experience to testify regarding biomechanical engineering, has not assured the court that the methodology he employed in his initial report is reliable, and Zimmer's motion to exclude that portion of his testimony is granted. The opinions offered in Dr. Fetto's rebuttal report to Zimmer's expert, Dr. D'Lima, however, are within the scope of Dr. Fetto's expertise, are based on sound reasoning, and will be admitted.[8]

With respect to Zimmer's motions for summary judgment, the court concludes that Ms. Batty's claim of strict liability design defect is not cognizable as a matter of Pennsylvania law, and Zimmer is entitled to judgment on that claim. Because the amount of flexion Ms. Batty ultimately achieved with her knee implants is disputed, however, Plaintiff's "high-flexion" theories of femoral loosening survive summary judgment. Accordingly, Zimmer's motion for

[8] Dr. Fetto also provided his medical opinions regarding Ms. Batty's treatment in a separate report. Zimmer has not challenged the admissibility of this report and it is, therefore, admissible.

summary judgment on multiple grounds [1306] is granted with respect to Ms. Batty's strict liability claim, but denied with respect to Ms. Batty's negligent design defect claims and Zimmer's motion for summary judgment on femoral loosening [1317] is likewise denied. As noted earlier, ruling is reserved on Zimmer's remaining arguments for summary judgment.

DISCUSSION

I. *Daubert* Standards

Rule 702 of the Federal Rules of Evidence, which governs the admissibility of expert testimony, states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> > (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> >
> > (b) the testimony is based on sufficient facts or data;
> >
> > (c) the testimony is the product of reliable principles and methods; and
> >
> > (d) the expert has reliably applied the principles and methods to the facts of the case.

In *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), the Supreme Court held that the Federal Rules of Evidence "assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Id.* at 597. This inquiry involves a "three-step analysis," which asks "whether the witness is qualified; whether the expert's methodology is scientifically reliable; and whether the testimony will 'assist the trier of fact to understand the evidence or to determine a fact in issue.'" *Myers v. Illinois Central R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010) (quoting *Ervin v. Johnson & Johnson*, 492 F.3d 901, 904 (7th Cir. 2007)). *See also Lapsley v. Xtek, Inc.*, 689 F.3d 802, 809 (7th Cir. 2012) ("Rule 702 requires that expert testimony be relevant, reliable, and have a factual basis—requirements that must be met before the jury is allowed to hear and perhaps be persuaded by the expert testimony.").

Daubert teaches that the reliability of an expert's methodology may be assessed by considering factors such as "(1) whether the scientific theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether a particular technique has a known potential rate of error; and (4) whether the theory or technique is generally accepted in the relevant scientific community." *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 431 (7th Cir. 2013) (citing *Daubert*, 509 U.S. at 593–94). *Cf. Stollings v. Ryobi Technologies, Inc.*, 725 F.3d 753, 766 (7th Cir. 2013) (''Rule 702's reliability elements require the district judge to determine only that the expert is providing testimony that is based on a correct application of a reliable methodology and that the expert considered sufficient data to employ the methodology.") Once an expert has identified a reliable methodology, the "expert still must faithfully apply the method to the facts at hand." *Brown v. Burlington N. Santa Fe Ry. Co.*, 765 F.3d 765, 772 (7th Cir. 2014). And, the expert must "rely on 'facts or data,' as opposed to subjective impressions." *Id.* The test for reliability is a flexible one, however, *Lapsley*, 689 F.3d at 810, and the trial judge may, but need not, consider the specific factors identified in *Daubert*. The *Daubert* factors are important "where they are reasonable measures of the reliability of expert testimony," *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999), but those factors do not apply "to all experts or in every case." *Id.* at 141. Further, the trial court, in fulfilling its "gatekeeping" role, retains discretion in choosing *how* to assess the reliability of the experts' testimony. *Id.* at 152.

An expert's testimony is relevant under Rule 702 if "it assists the jury in determining any fact at issue in the case." *Stuhlmacher v. Home Depot U.S.A., Inc.*, 774 F.3d 405, 409 (7th Cir. 2014). "Whether an issue is relevant in a case is a question of substantive state law; whether the specific evidence offered is relevant to resolving the issue is a procedural question governed by the Federal Rules of Evidence." *Stollings*, 725 F.3d at 767. Testimony may be relevant even where it involves "hypothetical explanation[s] of the possible or probable causes of an event." *Id.* (quoting *Smith v. Ford Motor Co.*, 215 F.3d 713, 718–19 (7th Cir. 2000)). Ultimately,

whether an explanation is credible in light of the facts of the case is left to the trier of fact. *Id.* at 719.

Finally, "Rule 702's requirement that the district judge determine that the expert used reliable methods does not ordinarily extend to the reliability of the conclusions those methods produce—that is, whether the conclusions are unimpeachable." *Stollings*, 725 F.3d at 765–66 (citing *Daubert*, 509 U.S. at 595). An expert may provide expert testimony based on valid and properly applied methodologies and still present a "conclusion that is subject to doubt. It is the role of the jury to weigh these sources of doubt." *Id*. "[T]he accuracy of the actual evidence is to be tested before the jury with the familiar tools of 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *Lapsley*, 689 F.3d at 805 (quoting *Daubert*, 509 U.S. at 596).

The court applies these standards in determining whether Dr. Brown and Dr. Fetto's opinions regarding Zimmer's NexGen Flex implants are admissible.

II. Report of Dr. Brown

Dr. Thomas D. Brown is a professor emeritus of Orthopedics and Rehabilitation at the University of Iowa. (Thomas Brown Exp. Rep. [1454-5], hereinafter "Brown Rep.," 1.) He has a B.S. in Mechanical Engineering from the University of Maryland and an M.S. and Ph.D. in Mechanical Engineering-Bioengineering from Carnegie-Mellon University in Pittsburgh. (*Id.*) Dr. Brown has served for nearly forty years as a professor in the fields of orthopedics and rehabilitation, biomedical engineering, mechanical engineering, and orthopedic biomechanics. (*Id.*) His research focuses primarily on orthopedic biomechanics, and he has published more than 1,000 articles and papers and given nearly 900 presentations at national and international engineering and orthopedic conferences. (*Id.* at 2.)

Plaintiff asked Dr. Brown "to examine biomechanical aspects of several products within the Zimmer NexGen total knee ('total knee arthroplasty' or 'TKA') system," and to "examine the design features of the NexGen High Flex knee—both the Cruciate Retaining (CR-Flex) and

Legacy Posterior Stabilized (LPS-Flex) versions, the [Minimally-Invasive Surgery ("MIS")] Tibia Model 5950, and the NexGen Gender Solutions (GS) knee." (Brown Rep. at 2–3.) Dr. Brown asserts that "many implantations of these devices in humans have undergone early aseptic loosening," and that he was retained to "provide biomechanical perspective on whether signature design features in each of these devices are consistent with having caused or substantially contributed to these aseptic loosening problems." (*Id.* at 3.)

Zimmer urges the court to exclude, under Federal Rule of Evidence 702 and *Daubert*, the following portions of Dr. Brown's anticipated trial testimony:

1. Dr. Brown's opinions that signature design characteristics of Flex femoral implants render either the tibial or the femoral components susceptible to premature loosening;

2. Dr. Brown's opinion that a "failure cascade" would proceed from isolated areas of stress at the cement/device or cement/bone interface to lead to loosening of the femoral component; and

3. Dr. Brown's opinion that the extra two millimeter bone cut required for implantation of the Flex design may affect fixation strength or stability of the femoral component.

(Mot. to Exclude Dr. Brown [1298].) Zimmer does not challenge Dr. Brown's qualifications as a biomedical engineer (Def.'s Mem. in Supp. of Mot. to Exclude Brown [1302], hereinafter "Brown Mem.", 5), but does argue that Dr. Brown's methodology is unreliable and that his conclusions are not relevant to the issues on appeal. For the reasons discussed below, all of Zimmer's objections to Dr. Brown's testimony are overruled.

A. Femoral Loosening

Zimmer first challenges Dr. Brown's opinion that the "NexGen CR-Flex and LPS-Flex implants have signature design features that, to a reasonable degree of certainty, are biomechanically consistent with a substantially increased risk of aseptic loosening on the femoral side" of the device. (*Id.* at 7 (emphasis removed).)

1. Posterior Edge Loading and Cascade Failure

Dr. Brown asserts that Zimmer's NexGen Flex series creates posterior edge loading on the implant's articular tray,[9] which generates sufficient stress on the femoral fixation interface[10] to cause loosening. (*See, e.g.*, Dep. of Dr. Brown, Ex. A to Brown Mem. [1302-1], hereinafter "Brown Dep.", 13:14–14:14; 97:18–98:10; 105:21–107:22.) This conclusion, Dr. Brown explains, rests on several premises. The first is that "[i]n weight-bearing situations, high-flexion maneuvers place far greater mechanical demands upon the knee than occur for low- or moderate-flexion activities." (Brown Rep. at 14.) In addition, the large force generated by such maneuvers "pulls the tibial and femoral articular surfaces together very forcefully in the vertical direction, with that large contact force being concentrated within just a small area of contact at the posterior margin of those two surfaces." (*Id.* at 15.) This combination of large forces being brought to bear on a small surface area on the posterior, or back, edge of the articular tray of the implant, according to Dr. Brown, is one potential cause of femoral loosening. (*See id.* at 43; Brown Dep. at 105:21–107:9.)

Dr. Brown cites several studies for these assertions. One such study attempted to quantify the overall force that a knee joint generates in deep flexion. *See, e.g.*, Nagura T. et al., *Tibiofemoral Joint Contact Force in Deep Knee Flexion and Its Consideration in Knee Osteoarthritis and Joint Replacement*, 22 J. Applied Biomech. 305, 315 (2006) (hereinafter, "*Nagura*"). The *Nagura* researchers studied 16 healthy individuals (seven women and nine

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[9] An articular surface is any location where two skeletal structures (bones or cartilage) intersect. (*See* http://medical-dictionary.thefreedictionary.com/articular+surface) (last visited May 21, 2015).) An artificial knee implant's articular tray is a synthetic, polyethylene insert that is the point of contact between the femoral and tibial components in Zimmer's NexGen device. (*See* Ex. D. to D'Lima Ex. Rep. [1302-10], 3.)

[10] The implant's fixation interface, Dr. Brown explains, "is the zone of attachment between the implant and the host bone. . . . For cemented fixation, this term refers to the transition between the implant and the layer of cement, and/or between the layer of cement and the host bone." (Brown Rep. at 8 n.2.)

men) with healthy knees and found that the average peak contact force in the subjects' native knees during deep squatting was approximately 7.3 times a person's body weight. This amount of force is important, Dr. Brown asserts, because "[m]echanically, the direct cause of fixation interface loosening is that the stresses (effectively, the *intensity* of force, which is measured in force per unit area) which are developed at the interface exceed the interface's failure strength." (Brown Rep. at 25 (emphasis in original).)

In a second study Dr. Brown cites, the researchers attempted to model the failure risk of the femoral component for high-flexion knee implants. *See* Zelle J. et al.*, Does High-Flexion Total Knee Arthroplasty Promote Early Loosening of the Femoral Component*, 29 J. Orthop. Res. 976, 983 (2011) (hereinafter, "*Zelle*"). While Dr. Brown is careful to acknowledge that *Zelle* did not examine Zimmer-specific devices, he reasons that "the salient features of the[] respective flex designs are similar enough that [*Zelle*] provide[s] usefully instructive insight regarding interface fixation stress phenomena in high-flexion TKA designs." (Brown Rep. at 28.) According to Brown, *Zelle* found that for flexion angles between 120 and 145 degrees, the forces exacted on the femoral component exceed the component's failure strength, which can cause femoral loosening. (*Id.*) In Dr. Brown's view, the estimates in the *Zelle* study are conservative because the study did not account for any increased loading that might occur from condylar lift-off[11] or limited axial rotation[12] of high-flex implants, which would further concentrate

[11] The bottom of each femur has two "condyles"—or rounded prominences—that enable the femur to "articulate," or move easily, along the top of the tibia as the knee flexes. Typically, both condyles—medial (inner) and lateral (outer)—rest on the tibia, and the force from the femur is shared among the two condyles, roughly equally. (Brown Rep. at 38.) Condylar lift-off occurs when one of the femoral condyles lifts off of the tibia, causing the second condyle to absorb the entire tibio-femoral load. (Brown Rep. at 38.) For the condyle still touching the tibia, condylar lift off "roughly double[s] the load passing through that condyle, relative to the designer's intent." (Brown Rep. at 38.)

[12] Relative to native knees, Dr. Brown explains, "high flex TKRs have conspicuously reduced axial rotation at high flexion angles." (Brown Rep. at 40.) Axial rotation in this context refers to the tibial bone rotating internally as a joint flexes. Further, he continues,

(continued . . .)

the forces passing through the implant. (*Id.*) Dr. Brown notes further that *Zelle*'s model relied on a single loading event, when in real life, "the interface would experience many repetitive such cycles of loading," and which likely would have shown much higher loosening rates, Dr. Brown contends. (*Id.*)

Dr. Brown points out that the modeling results described in the *Zelle* study comport with femoral loosening observed clinically in other studies. He cites H. S. Han et al., *High Incidence of Loosening of the Femoral Component in Legacy Posterior Stabilized-Flex Total Knee Replacement*, 89-B J. Bone Joint Surg. 1457, 1461 (2007) (hereinafter, "*Han-1*"). *Han-1* studied 72 NexGen LPS-Flex fixed-bearing devices and found that 38 percent of these devices showed loosening after a minimum 30-month follow up, and that the patients who experienced loosening "tended to be people who were able to achieve higher degrees of flexion than were people whose implants had not loosened." (Brown Rep. at 8.) A follow-up report five years later on the same cohort found 46 percent of patients had required revision due to loosening, and these patients were those who could perform higher flexion activities relative to those patients who did not experience loosening. Han H-S, Kang S-B, *Brief Follow-up Report. Does High-Flexion Total Knee Arthroplasty Allow Deep Flexion Safely in Asian Patients?* 471 Clin. Orthop. & Rel. Res. 1492, 1497 (2013) (hereinafter, "*Han-2*").

Dr. Brown's methodology as it pertains to femoral loosening, then, consists of examining results found in both modeling and clinical studies, and drawing conclusions about the mechanisms of failure in the NexGen Flex series based on his analysis of this data. In

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> [T]o the extent that the implanted joint moves less than the corresponding native joint would have moved under equivalent external loadings, the implant necessarily provides motion restraint that prevents the full amount of motion that would otherwise have taken place. Such restraint necessarily requires development of "extra" force and/or torque within the implant, with those extra loads in turn needing to be transferred through the implant fixation interface, thus causing higher stress across that interface.

(*Id.*)

assessing the overall effectiveness of the NexGen high-flex design, he notes two important design differences between the Flex and Standard: (1) the Flex is intended for use at 155 degrees of flexion, while the Standard is designed to accommodate no more than 130 degrees of flexion; and (2) the Flex requires an additional two millimeter bone cut from the patient's femur.[13] (Brown Rep. at 25–26.) In Dr. Brown's estimation, these two changes explain why Zimmer's NexGen Flex designs are at "greater risk" of fixation interface loosening than the Standard designs.[14] (*Id.* at 25) He asserts that the use of the Flex design at greater degrees of flexion places more stress on the fixation interface. (*Id.* at 26.) At 130 degrees of flexion, for example, the tibio-femoral contact forces are significantly less (about 5.5 times a person's body weight) than at angles of flexion at around 155 degrees (about 7.3 times a person's body weight). The increased stress that accompanies greater flexion makes for a larger risk of loosening in the NexGen flex design relative to the Standard design, Brown maintains. (*Id.* at 25–26.)

In his deposition, as well as in his rebuttal report to Dr. D'Lima, Dr. Brown also opines that a failure of one portion of the interface may lead to a "failure cascade" across the rest of the implant-bone interface. In his rebuttal to Dr. D'Lima's expert report, Dr. Brown explains how the failure cascade arises:

> [O]nce a part of an interface fails and therefore is no longer able to transmit tensile or shear stresses, the remaining non-failed portions of the interface need to take up additional load. This load-shifting effect tends to be most acute for non-failed sites immediately adjacent to the failure patch, sites which themselves usually would tend to have already been stressed to near-failure levels. Thus, zones of interface failure physically tend to propagate.

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[13] Dr. Brown's opinion on the effect this additional two millimeter bone cut has on the integrity of the fixation interface is discussed *infra*, at Part II.A.2.

[14] On this point, the report does not distinguish femoral and tibial loosening. (*See* Brown Rep. at 25.)

(Brown Rebuttal to Dr. D'Lima Ex. Rep., Ex. K to Mot. to Exclude Brown [1302-11], hereinafter "Brown Rebuttal to D'Lima", 5.) That is, once the fixation interface fails at one spot, the load is transferred to other, adjoining points along the interface, which now must accommodate more force with less interface surface area, creating "progressive radiolucent lines,"[15] or loosening. (*See* Brown Dep. at 145:25–148:6.)

a. Reliability of Posterior Edge Loading Analysis

Zimmer offers several criticisms of the methodology underlying Dr. Brown's opinion that the femoral component experiences posterior edge loading. First, Zimmer contends that Dr. Brown's reliance on *Nagura* is unsound because patients could not have achieved the degree of flexion described in that study. (Brown Mem. at 7.) Zimmer relies on its own expert, Dr. D'Lima, who asserts that if patients truly achieved loads in deep squat of 7.3 times a person's body weight, as *Nagura* suggests, at least half of them would experience muscle failure or tendon rupture. (Mot. to Exclude Brown at 7 (citing Dep. of Dr. D'Lima, Ex. E to Mot. to Exclude Brown [1302-5], hereinafter "D'Lima Dep.", 231:4–23); *see also* D'Lima Dep. at 303:23–304:23.) Second, Zimmer continues, *Nagura*'s findings are less reliable compared to more recent research techniques that measure actual knee forces in humans. Third, *Nagura* used "young individuals with healthy, native knees, rather than total knee replacement patients." (Brown Mem. at 7.) Finally, according to Zimmer, *Nagura* did not consider that the total load a knee generates is reduced when the back thigh contacts the calf in deep flexion. (*Id.* at 8.)

Zimmer takes aim at Dr. Brown's reliance on other studies, as well. For instance, Zimmer argues *Zelle* does not support Dr. Brown's opinions because *Zelle* did not study Zimmer implants or have a control group. (*Id.* at 9–10.) Zimmer maintains that its implants are different enough from the implants studied in *Zelle* to make Dr. Brown's reliance on the study unreliable. (*Id.* at 9–10.) Zimmer also points to a competing study from the same laboratory that produced

[15] *See supra,* at 8 n.2.

Zelle, but that found no fixation interface failure under largely the same circumstances studied in *Zelle*. (*See* Brown Mem. at 13 (citing Van de Groes, et al., *Probability of Mechanical Loosening of the Femoral Component in High Flexion Total Knee Arthroplasty can be Reduced by Rather Simple Surgical Techniques*, 21 The Knee 209, 215 (2014), hereinafter "*Van de Groes*" ("In contrast to the study of Zelle et al. [7], the present study showed no direct failure of the cement-implant interface.").) But *Van de Groes* did find that a significant portion of the bone-implant interface (an area *Zelle* did not examine) was prone to loosening, which arguably is consistent with *Zelle*'s findings. (Pl. Resp. to Brown Mem [1452], hereinafter "Pl. Brown Resp.", 15.) And Dr. Brown offers criticisms of *Van de Groes* that may blunt the force of Zimmer's arguments as well. (*See, e.g.* Brown Errata Sheet at 4, 136:10–11 (explaining how the assumptions *Van de Groes* made in its model may have led to its finding that the cement-implant interface did not fail).)

In any event, whatever persuasive force Zimmer's arguments have, they are grist for cross-examination, not for eliminating Dr. Brown's testimony altogether. *Daubert*, 509 U.S. at 596. Dr. Brown relied on peer-reviewed literature that used modeling, a scientifically valid technique, to attempt to quantify the forces exacted on a knee joint in deep flexion. *See generally Nagura.* He relied further on peer-reviewed literature that modeled the forces that act upon the fixation interface of high-flex knee implants. *See generally Zelle*. He then used his expertise to connect the findings from such modeling with peer-reviewed clinical studies that have found statistically significant amounts of femoral loosening from NexGen Flex implants. *See Han-1; Han-2*. Reliance on such academic literature in formulating one's opinions is acceptable under *Daubert*. *Cf. Clark v. Takata Corp.*, 192 F.3d 750, 758 (7th Cir. 1999) ("Either 'hands-on testing' or 'review of experimental, statistical, or other scientific data generated by others in the field' may suffice as a reasonable methodology upon which to base an opinion." (quoting *Cummins v. Lyle Indus.*, 93 F.3d 362, 368 (7th Cir. 1996))). Zimmer will have ample opportunity at trial to attempt to discredit Dr. Brown's conclusions derived from such literature,

but for *Daubert* purposes, the court is satisfied that Dr. Brown's underlying methodology as it pertains to femoral loosening is sufficiently reliable to be admitted. *See Stollings*, 725 F.3d at 766 (noting that the jury's role is to decide whether to accept an expert's conclusion).

In reaching this conclusion, the court notes that Dr. Brown was careful in his report to acknowledge the limits of extrapolating from *Zelle*. He explained that, while the NexGen Flex implants have design features similar to the implants studied in *Zelle,* their differences make it "inappropriate to contend that the specific values of computed stress also apply exactly to NexGen-Flex designs." (Brown Rep. at 28.) Such qualification may diminish the ultimate force of Dr. Brown's conclusions, but it does not render his methodology unreliable. *See Lapsley*, 689 F.3d at 805. As Dr. Brown observed, *Zelle*'s modeling was consistent with the *Han* cohort study, which *did* examine Zimmer's NexGen-Flex implants. *Han-1* found that 38 percent of a Korean patient pool involving 72 NexGen LPS-Flex fixed-bearing devices experienced loosening after at least 30 months of using the device, and 46 percent experienced loosening after five years. Dr. Brown highlights a sample case in *Han-1*, in which radiolucencies appeared beneath both the anterior and posterior flanges of the femoral component. Significantly, *Han-1* reported that "patients who had had implant loosening tended to be people who were able to achieve higher degrees of flexion than were people whose implants had not loosened." (Brown Rep. at 8.) Thus, while the exact forces generated in *Zelle* may not apply to Zimmer's product, the study still supports his opinion regarding the causal relationship between posterior edge-loading at high flexion and femoral loosening.

Zimmer insists that its own expert, Dr. D'Lima, has developed a superior method for quantifying forces generated in deep flexion. This does not change the court's conclusion regarding Dr. Brown's opinion, as it mistakes reliability for credibility. (*See* Brown Mem. at 8.) Similarly, Zimmer's multiple citations to competing studies that may rebut Dr. Brown's conclusions are not persuasive in the context of a *Daubert* challenge. Rule 702 does "not require, or even permit, the district court to choose between . . . studies at the gatekeeping

stage. Both experts [are] entitled to present their views, and the merits and demerits of each study can be explored at trial." *Schultz*, 721 F.3d at 433. Zimmer is free to debate the accuracy of Dr. Brown's predictions, and juxtapose them both with Dr. D'Lima's allegedly superior methods, and with competing studies contradicting Dr. Brown's conclusions, before a trier of fact. But the mere existence of competing research does not automatically work to render Dr. Brown's methodology unsound.

Nor is it improper for Dr. Brown to rely on his expertise and experience to critique the testing that Zimmer itself conducted. For instance, Dr. Brown examined Zimmer's internal documents in an attempt to understand the engineering choices that underlay Zimmer's high flexion design. In his view, "conspicuously little if any engineering attention was directed toward evaluating the integrity of the implant fixation interfaces" (Brown Rep. at 14), an alleged oversight that is part of a central theory of Plaintiff's case: that the NexGen Flex design causes the fixation interface to fail, or loosen when it is actually used at high-flexion angles. Specifically, Zimmer did not try to evaluate the loosening risks in clinical trials or in cadaver studies, even though, according to Dr. Brown, "[a]ppropriate technologies" existed that could have flagged any potential issues with the high-flexion design. (*Id.*) Failure to utilize these methodologies was a misstep, Dr. Brown asserts, because the high-flexion design ventured into "'new territory' biomechanically in several regards." (*Id.*) The credibility of Dr. Brown's conclusions regarding Zimmer's testing are left for another day. The question here is whether the methodology underlying those conclusions—in the form of critiquing tests actually performed—is reliable. It is.

Finally, Zimmer criticizes Dr. Brown's "failure cascade" opinion, claiming it

> rests on a number of logical leaps, growing more speculative at each step. He starts from a modeled prediction that forces will be higher at some locations on the device, moves to a projection that the cement bond will fail at those areas, then to a supposition that this failure will spread to other areas, and finally to what is effectively a guess that the device as a whole will loosen—under some circumstances—which he does not specify.

(Brown Mem. at 11.) The court rejects Zimmer's argument on this issue. The science behind a failure cascade effect is a basic principle of biomechanical engineering. (*See Fatigue*, *Elements of Metallurgy and Engineering Alloys*, Ch. 14, ASM Int'l (2008), Ex. P to Pl.'s Resp. to Brown Mem. [1454-16]; Brown Rep. at 29.) And, *Han-1* found progressive radiolucent lines, that is, evidence of a failure cascade, in the femoral components in 38 percent of the 72 devices he studied. *See generally Han-1*. As Zimmer points out, Dr. Brown himself acknowledged he had established no method for determining when a failure cascade would occur. (Brown Mem. at 14 (citing Brown Dep. at 145:18–22 ("I have no way of knowing that. It would require some serious research to pull out a number for that.")).) His opinion is nevertheless sufficiently reliable to be admitted. *Cf. Stollings*, 725 F.3d at 767 (expert may provide "hypothetical explanation[s] of the possible or probable causes of an event." (quoting *Smith*, 215 F.3d at 718–19)); (s*ee* Brown Rebuttal to D'Lima at 5; Brown Dep. at 145:25–148:6.)

b. Relevance of Dr. Brown's Opinions

Zimmer next argues that Dr. Brown's "premise of extremely heavy loads in high flexion does not fit the facts" of Plaintiff Batty's case, because the maximum amount of flexion her treating physician measured was 128 degrees, which is below what Dr. Brown characterizes as "high-flexion." (*See* Brown Dep. at 13:22–14:18. ("My definition of high flexion would be beyond the range from about 120 to 130. Going beyond the range of 120 to 130 is high flexion.").) Zimmer is correct that in clinical settings, Batty's treating physicians and physical therapists never found her flexion to be higher than 128 degrees in one knee, and that the Zimmer Standard design, which Plaintiff argues is superior, itself allowed flexion up to 130 degrees.[16] But when his deposition is read in full, it is clear that Dr. Brown does not understand flexion to be accurately captured by bright-line metrics:

[16] The court discusses this issue in more depth in the context of Zimmer's motion for partial summary judgment *infra*, at Part IV.B.2.

Q. Well, if you go beyond the range of 120 to 130, basically you're going beyond 130; right? Or would you consider 121 to be high flexion?

A. My answer to that would be that it's going to be -- it could be individual-specific. So I'm a little bit reticent to slap a single numerical value that would pertain to all people, all situations. For example, to say anything beyond 130 is high flexion, I'd be not very comfortable with saying that. So I think that one needs to keep in mind a range.

Q. Well, then what are the characteristics of high flexion that you believe might apply to some people at a lower part of the range and some people at a higher part of the range?

A. I think anything that might cause a standard, NexGen standard to have an impingement event posteriorly would be getting into some high flexion conditions.

Q. Anything that might cause a NexGen standard event to have an impingement condition posteriorly; correct?

A. Yes.

(Brown Dep. at 13:4–24.) Dr. Brown has not offered an estimate as to how much extra loading must occur, or how many degrees of flexion must be achieved before the failure cascade begins. His opinion that the design itself created a concentrated load posteriorly, and that such increased loads can cause femoral loosening, nevertheless follows from a reliable methodology and is relevant to the issues in this case. Zimmer's motion to bar this testimony is denied.

2. Two Millimeter Bone Cut

Dr. Brown identifies another Flex design feature that may contribute to aseptic loosening: the requirement that the implanting surgeon remove an additional two millimeters of femur bone. "No good can come of this," Dr. Brown claims. (Brown Rep. at 31 (emphasis in original).) For one, Dr. Brown asserts, the additional bone cut is susceptible to physician error, which alone can compromise the integrity of the fixation interface, an issue that Dr. Brown felt Zimmer did not adequately study. (*Id.* at 32–33.) According to Dr. Brown, "there is no precedent for this add-on step in total knee implantation surgery." (*Id.* at 33 (emphasis in original).) Dr. Brown further opines that "the Flex fixation interfaces are weaker due to the extra 2-mm bone cut having shifted the interface to less-dense and thus weaker cancellous bone"

(*Id.* at 25–26),[17] which is "less structurally competent" than the bone at the point where the interface would be for the Standard knee replacement. (Brown Rep. at 37.) This weaker surface area is another potential cause of loosening, according to Dr. Brown. (*Id.* at 35–37.)

In reaching this opinion, Dr. Brown reviewed ten examples of CT scans taken of patient's femurs; he observed "localized pockets of reduced bone density" in the femoral condyle areas near the fixation interface area for the NexGen Flex implants. He observed "cold spots" (that is, less dense areas) in 80 percent of the knee CT scans he examined. (Brown Dep. at 195:1–196:16; Brown Rep. at 36.) Dr. Brown qualifies his assessment of the additional bone cut, however: "To be clear: My anecdotal observations are not intended as proof that the interface is shifted into weaker bone. Rather, they are simply intended to bring to light an issue of potential concern for enhanced interface failure risk that the Zimmer NexGen-Flex designers should have taken into consideration, but did not." (Brown Rep. at 37.) He notes, further, that though he does not know what prompted the change, the successor to the NexGen high-flex device, the Persona, abandoned the extra bone cut in its design. (*Id.* at 38.)

a. Reliability of Two Millimeter Bone Cut Opinion

Zimmer attacks Dr. Brown's opinion that the additional two millimeter bone cut exposes the implant interface to weaker bone than the cut required for the Standard design. (Mot. to Exclude Brown at 16.) In his deposition, Zimmer urges, Dr. Brown admits that the "evidence" on this issue is not sufficient for him to say the extra bone cut actually creates a problem:

> Q: Okay. So it should have been looked at and determined if it's a problem, but whether or not it truly is a problem you don't have an opinion?
>
> A: I have a suspicion, but . . .

[17] Cancellous bone is light-weight, porous bone that gives a "honeycombed or spongy appearance." *See* http://www.britannica.com/EBchecked/topic/92222/cancellous-bone (last visited May 19, 2015). The properties of cancellous bone allow it to "dampen sudden stresses, as in load transmission through the joints," and it is usually surrounded by more compact bone, which is stronger and more rigid. *Id.*

Q: I don't want to hear your suspicions. I want to hear if you have an opinion to a reasonable degree of certainty?

A: I'd have to say, I just don't know.

(Brown Dep. at 197:2–9.)

The issue is a close one in the court's view. Read in full, however, Dr. Brown's deposition testimony, in tandem with his report, satisfy the court that he has applied a reliable methodology to reach his conclusion that the two millimeter bone cut is a potential cause of aseptic loosening of Zimmer's implant components. *Cf. Stollings*, 725 F.3d at 767 (expert may provide "hypothetical explanation[s] of the possible or probable causes of an event." (quoting *Smith*, 215 F.3d at 718–19)). In his deposition, he explained that "if an interface is being created to support an implant, the further away from the subchondral plate[18] that interface is, the less dense the cancellous bone against which it abuts. And it's a relatively strong effect." (Brown Dep. at 172:10–14.) The decreasing density of cancellous bone is a "natural standard property of epiphyses,[19] in the human skeleton and all mammals." (Brown Dep. at 171:10–172:9.)

While the density of the human femur bone has not been "mapped" by scientists, Dr. Brown continues, it has been measured in other places in the human skeleton and in other mammals. (*Id.* at 172:15–173:2; *see* Brown Rep. at 34–35 (citing Harada, Y. et al., *Distribution of bone strength in the proximal tibia*, 3(2) J. Artho. 167, 175 (1988); Polk, J.D. et al., *Knee posture predicted from subchondral apparent density in the distal femur: An experimental validation*, 291(3) Anat. Rec. 292–302 (2008).) Dr. Brown's ultimate opinion is that Zimmer should have studied this issue in depth before proceeding with the Flex design. (Brown Dep. at

[18] The subchondral plate is bone that is more dense relative to cancellous bone. (*See* Brown Dep. at 171:19–172:9.)

[19] The epiphysis is the "expanded end of the long bones in animals," which is made of "spongy cancellous bone covered by a thin layer of compact bone." *See* http://www.britannica.com/EBchecked/topic/190126/epiphysis (last visited May 21, 2015).

191:15–192:7.) Zimmer disputes the studies Dr. Brown relies on, in particular *Polk*, because it studied the bone density of sheep, not humans. But the lack of data concerning the density of a human femur bone does not necessarily render Dr. Brown's methodology unreliable, as this too goes to weight, not admissibility. *Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

Further, his examination of "cold spots" on several CT scans provides methodological fodder for his conclusion that the two millimeter bone cut required by the Flex design may have contributed to aseptic loosening. Again, whether his conclusion is credible is not a question the court answers here; the court concludes only that Dr. Brown's methodology in arriving at his conclusion is sound. *Cf. Stollings*, 725 F.3d at 765–66.

b. Relevance of Two Millimeter Bone Cut Opinion

Dr. Brown's opinion on the two millimeter bone cut is relevant to the facts of this case because it is probative of whether the NexGen Flex device had signature design defects that contributed to Plaintiff's injuries. *Stuhlmacher*, 774 F.3d at 409 (an expert's testimony is relevant under Rule 702 if "it assists the jury in determining any fact at issue in the case.").

B. Tibial Loosening

Dr. Brown's anticipated trial testimony includes his opinion that the NexGen Flex series implants may cause not only femoral loosening but tibial loosening, as well. As he states in his report:

> The very large tibio-femoral contact forces developed due to posterior edge loading or near-edge loading in high flexion act not only on the femoral component, but also upon the tibial component. This is a direct consequence of Newton's 3rd Law, which states that for any force, there is an equal but opposite reaction force.

(Brown Rep. at 44.) Dr. Brown claims that "[a]voiding loosening of the tibial component is a classic design challenge in TKA," and he believes Zimmer did not adequately address this concern in its testing. (*Id.* at 48). Zimmer knew that high-flexion implants "would unavoidably

involve large loads concentrated at or near the posterior lip of the polyethylene tibial insert," Dr. Brown asserts, and did perform tests to study this issue. (*Id.* at 44–45.) The testing compared contact areas of the CR-Flex and CR-Standard implants, "the thinking being that if CR-Flex achieved contact areas as large as those for CR Standard (a clinically successful predicate device), the CR-Flex contact stresses (force per unit area) and contact areas would be within clinically acceptable limits." (*Id.* at 45.) The problem with these tests, he asserts, is that they assumed the same flexion levels for both devices (0, 10, 45, 90, 130, and 155 degrees), even though the CR Standard's flexion limit is 130 degrees, and the CR-Flex's limit is 155 degrees. (Brown Rep. at 45) That is, measuring the contact force of the CR Standard at 155 degrees has little utility, because the CR Standard implant is not meant to accommodate this much flexion. So even though the test results showed better performance of the CR Flex design at 155 degrees, it was not an "apples to apples" comparison. (*Id.* at 49.) Dr. Brown opines that Zimmer should have compared the Standard at its maximum flexion angle (130 degrees) with the Flex at its maximum flexion angle (155 degrees). (*Id.*) Such a comparison would have revealed that, at its maximum flexion angle, the Flex had a smaller contact area (116 mm^2) than the Standard design at its maximum flexion angle (149 mm^2). (*Id.* at 45–46.) The smaller contact area, coupled with increased force generated by the knee in deep flexion, makes the Flex more susceptible to tibial loosening than the Standard, according to Dr. Brown.

And further, the testing used "unrealistically benign loading" weights of 400 pounds, rather than the 720 pounds "normally used for TKA contact testing for walking gait simulations." (Brown Rep. at 46.) He goes on to criticize other Zimmer testing for similarly using unrepresentative loads. (*Id.* at 47.) Dr. Brown believes that more realistic testing would have demonstrated that the high-flexion implants would cause tibial loosening due to posterior edge loading. (*Id.* at 50.)

Another potential cause of tibial loosening that Dr. Brown discusses is a phenomenon known as "toggling," or "micro-motion." (*Id.* at 47.) Boiled down, the concept is that forces pass

"eccentrically or nearly eccentrically to the supporting fixation interfaces" of the tibial component. (Brown Rep. at 47–48.) In this context, "eccentric" refers to the movement of the contact point between the femur and tibia away from the center of the tibia. These eccentric forces cause the tibial component to "rock" or "toggle," leading to tibial loosening, he contends. (*Id.* at 48) Dr. Brown's chief complaint about Zimmer's testing in this regard is the same mentioned above: Zimmer compared the Standard and high flexion implants' risk of micro-motion both at 155 degrees, even though the Standard device is not designed to flex that far. (*Id.* at 49.) And the testing used the same load force for both designs, even though a correspondingly larger contact force for the CR-Flex in deep flexion would have allowed for more meaningful comparison of micro-motion between the Standard and high-flexion designs. (*Id.* at 48–50.)

1. Reliability of Tibial Loosening Opinions

According to Zimmer, Dr. Brown's opinion on tibial loosening is not sufficiently reliable to satisfy *Daubert*'s strictures. (*See generally* Brown Mem. [1310].) In support of this objection, Zimmer relies heavily on a study conducted by its own expert for this litigation: Dr. Michael Vitale performed a literature review of studies that purportedly assessed whether high-flex implants are prone to aseptic loosening, and concluded that

> there is no defendable basis to question the safety of the NexGen Flex knee implants, as it relates to aseptic loosening or even in the context of all cause revision. On the contrary, there is ample evidence to suggest that NexGen Flex knee systems are among the highest performing products in this regard, and that there is no identifiable risk to preclude their continued widespread use.

(Mem. in Supp. of Mot. to Exclude Tibial Loosening [1310], 2.) Zimmer argues that Dr. Vitale's study is enough, on its own, to disqualify any expert opinion that Zimmer's implants cause tibial loosening.

The court disagrees that Vitale's litigation-driven literature review requires that Dr. Brown's opinion on tibial loosening be excluded. The lack of epidemiological evidence pointing to aseptic tibial loosening of the NexGen Flex implants does not make Dr. Brown's opinion on

the subject automatically unreliable. *See Smith v. I-Flow Corp.*, No. 09-cv-3908, 2011 WL 12556366 (N.D. Ill. May 3, 2011), *3 ("There is no rule that requires an expert to base his causation opinion on an epidemiological study.") (Kennelly, J.). Rather, epidemiological evidence is one of many kinds of data that can inform an expert's methodology in arriving at a particular opinion. The methodology underlying Dr. Brown's tibial loosening opinion here mirrors the methodology underlying his conclusions about the biomechanical risks of femoral loosening. This court has already ruled that methodology is sufficiently reliable under *Daubert* to support Dr. Brown's opinions on femoral loosening, and it provides sufficient support for his opinion on tibial loosening, too.

For his tibial loosening opinion, Dr. Brown starts with the general premise that as flexion increases in the knee joint, the tibio-femoral contact forces in the knee also increase. (*See* Brown Rep. at 47.) His other general premise is Newton's Third Law, the principle that for any force, there is an equal but opposite reaction force. He then connects these general premises to the NexGen Flex tibial component—opining that when the loads associated with these forces reach the posterior edge of the tibial articular surface of the implant, the forces act not only on the femoral component but also on the tibial component, and have "the tendency to cause the tibial component to 'rock' or 'toggle'," that would "tend to pose a substantial challenge to fixation interface integrity." (*Id.* at 47–48.) Moreover, at key flexion angles, Dr. Brown noted, the contact area is *smaller* with the Flex design than with the Standard design, resulting in an increase in pressure on the tibial component's fixation interface. (Brown Rep. at 46.) Zimmer dismisses this reasoning, but the court concludes it is reliable and relevant; it explains *why* the Flex has a greater risk of tibial loosening than the Standard and provides a sufficiently reliable basis for Dr. Brown's opinion.

Dr. Brown also sharply criticizes Zimmer's internal testing that compared the amount of micro-motion that could occur at 155 degrees for both the Standard and NexGen Flex knee. (*Id.* at 21 (citing Zimmer Tech. Memo Z007171–180).) As noted earlier, he points out that the

Standard was not intended for use beyond 130 degrees, so it is unclear what Zimmer intended the test results to show. As Dr. Brown explains:

> Zimmer took the position that since there was nothing in the CR Standard design per se that actively prevented the implant from being flexed to 155°, it would be appropriate to make head-to-head comparisons of both implants at 155°. Such a formalistic basis for comparison might perhaps be rationalized from the standpoint of deliberately trying to downplay whatever degree of increased micro-motion propensity might actually exist for CR-Flex. But in my opinion, such a basis of comparison is difficult to justify from the standpoint of providing meaningful insight into these two designs' relative micro-motion propensity under *in vivo* usage conditions.

(Brown Rep. at 49–50.)

Zimmer attempts to deflect this criticism by emphasizing Dr. Brown's recognition that it would be relatively safer to use a NexGen Flex device than a Standard device for patients who sought to achieve high flexion:

> Q. Would you agree that if a NexGen standard device is flexed to a range of 130 or up, that it is safer to do that with a NexGen-Flex than a NexGen standard?
>
> A. So if you know that you're going to go beyond 130, would you rather have it happen with a NexGen-Flex than a NexGen standard? I think that's a no-brainer. You want the Flex.

(Mem. in Supp. of Mot. to Exclude Tibial Loosening at 13 (citing Brown Dep. at 84:2–9).) As the court understands Plaintiff's theory, however, Dr. Brown's opinion here champions the NexGen Flex design over the Standard only in a relative sense. In his deposition errata sheet, Dr. Brown clarified his remarks on the issue: "But just because I think the NexGen-Flex might be safer than the standard does not mean I think the NexGen-Flex is safe at 130 or up." (*See* Brown Dep. Errata Sheet, Ex. N to Rusch Affidavit [1454-10], 3.)

Certainly an epidemiological study linking the NexGen Flex implants to tibial loosening would bolster Dr. Brown's report. Even without such a study, however, the court concludes that a jury trial is the appropriate forum to test Dr. Brown's opinions on tibial loosening. *See Lapsley*, 689 F.3d at 817 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky

but admissible evidence." (quoting *Daubert*, 509 U.S. at 596)). Zimmer will be free to assert its reasons for conducting the testing in the way it did, just as Dr. Brown is free to criticize the testing Zimmer did do, and also to infer what the consequences of different or additional testing might have revealed. Such criticisms are probative of Plaintiff's negligent claims, as discussed below. *See infra*, at Part IV.B. Similarly, Zimmer's argument concerning the lack of epidemiological evidence pointing to tibial loosening may well have purchase with a trier of fact. But such a contention affects the credibility, and not admissibility, of Dr. Brown's tibial loosening opinions.

The court offers a few other observations about Zimmer's *Daubert* challenge to Dr. Brown's tibial loosening opinions. Zimmer criticizes Dr. Brown's unsupported "leap" from the premise that a body generates high levels of force in deep flexion to the conclusion that "such loads will be placed on the posterior edge of the articular surface . . . causing anterior lift-off of the tibial implant," resulting in "high stresses at the implant/cement/bone interfaces." (Brown Mem. at 9.) According to Zimmer, this logical connection is unsupported because Dr. Brown did not do any testing or modeling himself. (*Id.*) True enough, but *Daubert* does not require an expert to conduct his own studies for the expert's opinion to be admissible. *See Clark*, 192 F.3d at 758; *Smith*, 2011 WL 12556366, at *3 (concluding that it was permissible for an expert to "rel[y] on a significant number of peer-reviewed studies that, taken as a whole, suggest an association between [the mechanism at issue and the resulting injury."). Further, he offered a plausible critique of Zimmer's own internal testing (*see* Brown Rep. at 46–47), and explained what alternative testing protocol would have revealed, namely, that the high-flexion design Zimmer selected was prone to tibial loosening.

And finally, *Fuesting v. Zimmer, Inc.*, 421 F.3d 528 (7th Cir. 2005), cited repeatedly throughout Zimmer's briefs, does not change the court's conclusion. In that case, the plaintiff filed products liability claims against Zimmer after one of his knee implants caused pain and swelling and was replaced with a different device. *Id.* at 531. At trial, the district court admitted

testimony of the plaintiff's expert that gamma irradiation (a sterilization method) of the polyethylene tray contributed to the implant's failure. *Id.* at 531. The expert's conclusion rested on a basic scientific principle: that "gamma irradiation of polyethylene can create free radicals that bond with oxygen, thereby decreasing its molecular weight by keeping molecular chains from re-forming, increasing its density, and making the polyethylene susceptible to delamination." *Fuesting*, 421 F.3d. at 536. In vacating the jury's verdict in favor of the plaintiff, the Seventh Circuit noted that (a) the expert "did not conduct any scientific tests or experiments to bolster his theory relating to polyethylene delamination to gamma irradiation in air"; (b) he did not "produce or rely upon any studies to verify his conclusion"; and (c) he made an "unjustif[ied] extrapolation from an accepted premise to an unfounded conclusion" when he claimed that "basic polymer science" informed his conclusion about the cause of polyethylene delamination. *Id.*

In contrast, while Dr. Brown did no testing of his own, he relied on scores of studies and references to inform his opinion about the cause of aseptic loosening in patients with the Zimmer NexGen Flex implant. (*See* Brown Rep. at 63–74.) He did not argue that Newton's Third Principle controls on the question of tibial loosening; instead, he linked that principle, through data and peer-reviewed articles, to his theory about how the tibial component may loosen through toggling or micro-motion, and also through posterior edge loading of the articular tray. (*See* Brown Rep. at 47–48.) Unlike the expert in *Fuesting*, Dr. Brown has "bridge[d] the analytical gap between these basic principles and his complex conclusions." *Cf. Fuesting*, 421 F.3d at 536. Nor is Dr. Brown's "theory" about tibial loosening of the sort that the scientific community rejects. There are no epidemiological studies that have identified the problem, but Zimmer's own experts conceded that Newton's Third Law governs the forces that are brought to bear on knee implants. (*See, e.g.*, D'Lima Dep. at 118:24–119:6.) In short, Dr. Brown provided a clear methodological roadmap of his analysis. Where methodology is reliable, "[i]t is the role

of the jury to weigh the[] sources of doubt." *Stollings*, 725 F.3d at 765–66. Zimmer's motion to prohibit Dr. Brown from testifying on tibial loosening is, therefore, denied.

2. Relevance of Tibial Loosening Opinions

Dr. Brown's tibial loosening opinion is relevant to the facts of this case. Plaintiff alleges she had tibial loosening, and Dr. Brown's opinion is probative of whether the NexGen Flex device had signature design defects that contributed to such loosening. *See Stuhlmacher*, 774 F.3d at 409 (an expert's testimony is relevant under Rule 702 if "it assists the jury in determining any fact at issue in the case.").

III. Report of Dr. Fetto

Plaintiff offers the testimony of Dr. Joseph Fetto, an orthopedic surgeon, to establish that the NexGen Flex implant suffered from a design defect; that Zimmer inadequately tested its product before bringing it to market; that even with the inadequate testing, Zimmer was on notice of a design defect and continued to market the high-flex knees; and that Zimmer's warnings regarding the risk of aseptic loosening were insufficient. To reach his conclusions, Dr. Fetto relied on his understanding of the anatomy and kinematics of the knee, his review of published literature regarding total knee arthroplasties, and his review of Zimmer's internal documents and several depositions taken in this case. (Fetto Exp. Report, Ex. A to Zimmer Mot. to Exclude the Testimony of Dr. Fetto [1301-1], hereinafter "Fetto Rep.," 2.)

Dr. Fetto submitted several rebuttal reports, as well, including a criticism of the Finite Element Analysis (FEA)[20] conducted by Zimmer's expert, Dr. Daryl D'Lima. Based on his review of Ms. Batty's medical records, Dr. Fetto opines that the cause of her failure was aseptic loosening. Zimmer does not challenge Dr. Fetto's medical opinions about Ms. Batty, but seeks

[20] An FEA is a computer model used to predict how an implant will function under certain conditions. Dr. Daryl D'Lima created an FEA to model the NexGen implants in order to predict how various stresses and forces would affect the interfaces where the implant attaches to the bone.

to exclude his opinions related to (a) biomedical engineering, (b) Dr. D'Lima's computer model predicting forces acting on the implant, (c) FDA regulations and pre-market testing, and (d) the adequacy of Zimmer's warnings. Zimmer contends that those opinions are outside the scope of Dr. Fetto's expertise and that his methodology is unreliable. (Zimmer's Second *Daubert* Mot. [1300]; Zimmer's Mem. of Law in Supp. of its Second *Daubert* Mot. [1301], hereinafter "Zimmer Fetto Mem.," 1.)

The court concludes that Dr. Fetto's experience qualifies him to offer opinions related to biomechanical engineering and to provide limited evaluations of FEA models. Dr. Fetto has presented a reliable and relevant rebuttal to Dr. D'Lima's FEA model and the court denies Zimmer's motion on that point. Though the remainder of his testimony is relevant, the court cannot discern any reliable methodology supporting Dr. Fetto's opinions regarding the design defect, the risk of aseptic loosening, or the adequacy of Zimmer's testing, and concludes that those opinions must be excluded. His opinions regarding the adequacy of Zimmer's warnings must also be excluded because they are not based on sufficient facts: it is not even clear from his testimony that Dr. Fetto actually read the package inserts containing Zimmer's warnings.

A. Qualifications

Dr. Joseph Fetto is a board-certified orthopedic surgeon at New York University Medical Center. (Fetto Rep. at 2.) He earned a Bachelor of Science in Chemistry from the State University of New York at Buffalo and began—but did not complete—a graduate program in Engineering at the same university before entering New York Medical College, where he completed medical school in 1974. (*Id*.) Before leaving graduate school, Dr. Fetto completed 18 credits hours of engineering coursework, six in biomechanical engineering, and the rest in mechanical engineering; he has completed no additional courses in engineering. (Dep. of Dr. Joseph Fetto, Ex. B to Zimmer Mot. to Exclude the Testimony of Dr. Fetto [1301-2], hereinafter "Fetto Dep.," 21:25–22:18.) After medical school, Dr. Fetto completed a Fellowship in Sports Medicine and completed surgical and orthopedic residency at the Hospital for Special Surgery in

New York in 1979. (Fetto Rep. at 2.) Since then, Dr. Fetto has devoted 10 to 15 percent of his time to research and teaching residents and fellows in the adult reconstructive fellowship program of New York University Medical Center and the Hospital for Joint Diseases. (Fetto Dep. at 23:22–24:8, 40:1–9; Fetto Rep. at 2.) Dr. Fetto spends 85 to 90 percent of his work in private practice, performing total joint replacements, primarily at New York University Langone Medical Center. (Fetto Dep. at 39:3–7; 40:1–9.) As part of his clinical practice, Dr. Fetto estimates that he performs an average of 100 total knee replacements each year, comprising roughly 40 percent of the total joint replacement surgeries he performs.[21] (*Id*. at 43:14–19.) Dr. Fetto has never implanted a Zimmer NexGen device, however, preferring to use the "3D" device made by DJO Surgical. (*Id*. at 43:25–44:3, 44:21–45:1.)

Dr. Fetto has written or co-authored several articles on the biomechanics of hips[22] but has never conducted a study on a high-flex or any other knee implant. (*Id*. at 99:6–23.) He has written two articles pertaining to the "very unusual" condition of yeast abscesses in total knee replacements, but admits those articles are "[n]ot relevant" to his opinions in this litigation. (Fetto Dep. at 85:10–15.) He has also authored a leading textbook on the musculoskeletal system, given over 200 invited lectures—several explicitly relating to the biomechanics of the hip and lower extremity[23]—and consults with biomechanical engineers in NYU's Biomechanics

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[21] Dr. Fetto estimates that 50 percent of his replacement surgeries involve hips and the remaining 10 percent involve shoulders. On rare occasions he performs elbow replacement surgery. (Fetto Dep. at 43:14–19.)

[22] Dr. Fetto has authored several articles that apparently address biomechanics including, for example, articles titled "A New Approach to the Biomechanics of the Hip: The Introduction of the Iliotibial Band," the "Biomechanics of the Hip," and "Evolution of the Koch model of the biomechanics of the hip; clinical perspective," as well as two articles published in the Journal of Biomechanical Engineering. (Dr. Fetto CV, attached to Fetto Report [1301-1] at 4–8.)

[23] A sample of the titles of Dr. Fetto's presentations include: "The Biomechanics of Joint Replacement"; "Biomechanics of the Lower Extremity: Prosthetic Design Implications for Amputees"; "Re-examination of Biomechanics During Unilateral Stance"; "Biomechanics of the Lower Extremity"; and "Applied Biomechanics of the Lower Extremity." (Fetto CV at 8–26.)

lab, including one of Zimmer's experts, Dr. Peter Walker. (*Id*. at 99:16–23, 106:6–10; Fetto Curriculum Vitae at 8–26.)

Dr. Fetto has experience in orthopedic implant design: he conceptualized, designed, and obtained a patent for a portion of a hip implant, called the Lateral Flare stem. (Fetto Curriculum Vitae at 4.) He is currently participating in the design of a knee implant by a Zimmer competitor, Consensus. (Fetto Dep. at 32:4–5.) Dr. Fetto also serves on the Board of Directors of the International Society for Technology in Arthroplasty. (*Id*. at 222:5–7.) Zimmer argues that Dr. Fetto is not qualified to testify regarding biomechanical engineering because he lacks academic training in the field and has never published on an engineering topic related to the knee. (Zimmer Fetto Mem. at 2.) Zimmer notes, further, that Dr. Fetto has never implanted a Zimmer device, has never studied or quantified the forces or loads in any knee implant, and has never researched total knee replacement devices. (*Id.* at 3.) As the Seventh Circuit has observed, however, "while extensive academic and practical expertise in an area is certainly sufficient to qualify a potential witness as an expert, Rule 702 specifically contemplates the admission of testimony by experts whose knowledge is based on experience [as well]." *United States v. Parra*, 402 F.3d 752, 758 (7th Cir. 2005); see also *Smith v. Ford Motor Co*., 215 F.3d 713, 718 (7th Cir. 2000). Implanting Zimmer devices and conducting research is not the only way to develop an understanding of the biomechanics of knees and knee implants. Though Dr. Fetto does not have extensive academic training in biomechanical engineering, and has not specifically researched the biomechanics of the knee, his academic and clinical experience employing biomechanical principles satisfies the court that he is qualified to opine on biomechanical engineering topics.

B. Reliability of Dr. Fetto's Opinions

Zimmer contends that, even if Dr. Fetto is qualified, his opinions should be excluded because they are not based on any reliable methodology. Zimmer challenges (1) Dr. Fetto's criticisms of Dr. D'Lima's Finite Element Analysis; (2) his engineering opinions regarding the

tendency for Zimmer's high-flex components to loosen; (3) his opinions that Zimmer's pre-market testing was inadequate; and (4) his criticism of Zimmer's warnings and package inserts. The court evaluates each of these opinions in turn.

1. Dr. Fetto's Criticisms of Dr. D'Lima

Zimmer urges the court to exclude Dr. Fetto's criticisms of Dr. D'Lima's Finite Element Analysis because Dr. Fetto is not an FEA expert. Indeed, Dr. Fetto admitted that he is not trained to construct FEA models and that he has never been involved in modeling an FEA for the total knee. As he explains:

> I had been involved in some very, very rudimentary academic exposure to these things, but I have not, at today, any of the expertise required to formally go through all the computer mathematical analysis that's required. So I leave that to the engineers. . . . I recognize my limitations and I don't think I'm expert enough to construct an FEA to today's standards.

(Fetto Dep. at 104:13–24.) Zimmer also highlights Dr. Fetto's statement that "I don't know if I'm qualified to level a critique about how good or bad [Dr. Zelle's FEA model] was. I certainly respect it as one of the FEA models of knees making certain predictions . . . But in terms of saying it was good or bad, no I think that would be a qualitative judgment I wouldn't . . . be able to make." (*Id*. at 412:1–8.)

Consistent with these acknowledged limitations, Dr. Fetto has not addressed the mathematical analysis used by Dr. D'Lima nor made broad, qualitative statements concerning that analysis. Rather, Dr. Fetto focuses on particular aspects of Dr. D'Lima's model which, in his view, undermine its applicability to a wide range of patients. First, he criticizes Dr. D'Lima's boundary conditions and assumptions about what would cause failure. According to Dr. Fetto, Dr. D'Lima's model assumes that failure of the implant-bone interface "only occurs if more than 0.5 mm of movement occurs between the prosthesis and the underlying bone and/or cement." (Fetto Rebuttal to Dr. D'Lima, Ex. F to Zimmer Fetto Mem. [1301-6], hereinafter "Fetto Rebuttal to Dr. D'Lima," 1.) That assumption, Dr. Fetto contends, does not comport with academic literature documenting micromotion. He cites five studies that associate micromotion greater

than 0.15 millimeters with aseptic failure. Thus, in Dr. Fetto's view, Dr. D'Lima's model underestimates the likelihood of failure. (Fetto Rebuttal to Dr. D'Lima at 1.) This appears to be precisely the kind of input that Dr. Fetto would provide to an engineer constructing an FEA, and the court finds it reliable.

Dr. Fetto also criticizes Dr. D'Lima's failure to validate the model in high-flex ranges and notes that Dr. D'Lima's model does not predict femoral failure, which has been documented in clinical studies. (Fetto Rebuttal to Dr. D'Lima at 2.) In Dr. Fetto's opinion, the mismatch between the FEA predictions and the clinical results undermines the validity of the FEA's prediction. (*Id.*) Zimmer responds that Dr. D'Lima's model is more sophisticated than models that Dr. Fetto cites in his original report and notes that Dr. Fetto did not attempt to "fill the gap[s]" he identified in Dr. D'Lima's model. (Zimmer Fetto Mem. at 20.) These criticisms, however, do not address Dr. Fetto's methods for evaluating Dr. D'Lima's model, but rather address the weight that a jury should give to Dr. Fetto's criticisms and to Dr. D'Lima's model. "Assuming a rational connection between the data and the opinion . . . an expert's reliance on faulty information is a matter to be explored on cross-examination; it does not go to admissibility." *Walker v. Soo Line R.R. Co.*, 208 F.3d 581, 589 (7th Cir. 2000). "Our system relies on cross-examination to alert the jury to the difference between good data and speculation." *Schultz*, 721 F.3d at 432. Dr. Fetto's rebuttal to Dr. D'Lima's FEA analysis is admissible, and Zimmer will have an opportunity to raise its criticisms on cross-examination.

2. Dr. Fetto's Opinions that Zimmer's Design Causes Aseptic Loosening of the Femoral and Tibial components

Dr. Fetto opines that when Zimmer began marketing its high-flex knees, there were "well established biomechanical principles which seriously questioned the feasibility of providing a 'safe' high flexion arthroplasty device." (Fetto Rep. at 2–3.) Specifically, Dr. Fetto notes that in high flexion—that is, when the knee bends deeply—there is greater force and pressure passing through the knee joint than when the knee is straight. (*Id*. at 4.) According to Dr. Fetto, the

design of the Zimmer knee, specifically the location of the tibial post[24] in Zimmer's high-flex "Posterior Stabilizing" or "PS" devices "forces loading onto the posterior margin of the tibial component" and reduces overall contact area between the femoral and tibial components. (*Id*.) The smaller contact area on the back of the tibial plateau, combined with the higher compressive loads that occur during high flexion, produces a lift-off stress on the front of the tibial component, "increasing the potential for compromise of either the cemented or non-cemented fixation of the tibial component." (*Id*.) That is, according to Fetto, as the compressive forces on the knee increase in high flexion, force is concentrated toward the back of the tibial plate, causing a corresponding upward force on the front of the tibial plate. This upward force—or "lift-off stress"—strains the bond between the tibial component and the tibial bone.[25] The result, according to Dr. Fetto, is "predictable failure of fixation in both the tibial and femoral components of a high flexion arthroplasty." (*Id*.)

Zimmer argues that Dr. Fetto's methodology in arriving at these conclusions is unreliable because he "cites no experiments, no published literature, no studies, no accepted standards, and no other sources with any indicia of reliability to support his opinions" about loosening. (Zimmer Fetto Mem. at 8.) Plaintiff responds that Dr. Fetto followed "the classic scientific regimen" of starting from a null hypothesis—that is, assuming that there is no difference between Flex and Standard knees—and "examining the Zimmer documents and published

[24] There are two kinds of tibial components: Posterior Stabilized ("PS") and Cruciate Retaining ("CR"). In a natural knee, when the knee bends deeply, the posterior cruciate ligament (PCL) helps stabilize the knee by preventing the femur from moving too far forward. Without this resistance, the knee would buckle. A CR knee retains the PCL, and the PCL continues to serve this stabilizing function post the knee replacement. In a PS device, however, the PCL is removed and the knee must be stabilized in another way. The tibial components of these devices, therefore, have a "post" that fits into a groove on the femoral component. In the absence of the PCL, the post on the tibial component is what prevents the femur from moving too far forward when the knee flexes.

[25] For tibial components that are cemented, the stress can cause debonding between the component and the cement or between the cement and the bone.

literature" to test that hypothesis. (Pl.'s Resp. to Fetto Mot. [1457], hereinafter "Pl. Fetto Resp.," 7.) When he completed this examination, Dr. Fetto testified, he found support in "reports, public and otherwise, [and] internal documents," for the conclusion that "there is an increase in pressure posteriorly, eccentrically, and that clinically there is an increased failure in the high-flexion devices over standard devices . . . So . . . my null hypothesis was rejected . . . Therefore, the conclusion is that high-flexion devices are associated with increased revisions." (Fetto Dep. at 270:12–271:13.)

The court acknowledges that Dr. Fetto cites several studies and documents suggesting that the high flex designs increase posterior loading of the tibial plateau in high flexion. The court also agrees that he cites several studies showing a higher revision rate for Zimmer high flex knees than for non-flex knees—specifically studies by *Han*, *Kang*, and *Namba*.[26] (*See* Fetto Dep. at 306:23–307:7.) Dr. Fetto has not, however, sufficiently explained why he sees a link between the higher revision rates and the evidence of posterior loading. The court does not understand what basis Dr. Fetto has for two critical steps of his analysis: (1) he has not explained the basis for his opinion that posterior and eccentric loading of the tibial tray causes the increased rate of revisions in high-flex knees, and (2) he has not sufficiently explained why the Zimmer high-flex *design*, as opposed to high flexion generally, creates an increased risk of posterior edge loading. The court addresses each problem in turn.

[26] Dr. Fetto did not provide specific citations to these three studies in his deposition, but the court understands his testimony to refer the following studies, which are cited in his expert report: (1) "Kang S, Are high flexion activities after High-Flex knee replacements safe? J Bone Joint Surg BR Vol 92-B, Issue SUPP_II, 322;" (2) "Namba RS, et al. Increased risk of revision of high flex TKA with thicker tibial liner. J Bone Jt. Surg. (2014);96-B:217-222;" and (3) "Han HS, High incidence of loosening of the femoral component in legacy posterior stabilised-flex total knee replacement. Bone Joint Surg. Br. 2007 Nov;89(11):1457-61." (Fetto Rep. at 59–64, references 27 (*Han*), 35 (*Kang*), and 79 (*Namba*).)

a. Dr. Fetto Cannot Explain Why He Believes Posterior and Eccentric Loading Causes Aseptic Loosening

Dr. Fetto's report begins with a discussion of the anatomy and kinematics of the knee, describing the location and function of the various soft tissues, muscles, ligaments, and cartilage. As the report explains, the knee is an unusual joint, whose stability depends on the soft tissues surrounding it, rather than on the bone structure. (Fetto Rep. at 7.) The report goes on to describe the basic biomechanics of the knee: when an individual is standing, the body's center of gravity is positioned directly over the knee and there is, essentially, a single compressive force passing through the center of the joint. (*Id*. at 14.) As the knee flexes, however, the body's center of gravity moves backwards—or posteriorly—in relation to the knee joint. The overall force on the knee also increases, to "significant magnitudes of as much as four, five, or six times body weight." (*Id*. at 18.) During flexion, the forces on the knee also become more complicated: Compressive forces from body weight continue to act on the knee, but simultaneously, the quadriceps muscles contract, pulling on the patella to resist the femur's forward motion, putting "shearing," "tensile," and "rotational" forces on the knee joint. (*Id*. at 15–16, 29–30.) Absent resistance from the quadriceps and patella, the femur would continue moving forward, into deeper flexion, causing the knee to buckle or give way. (Fetto Rep. at 16, 29.) As Dr. Fetto explains it, flexion also changes the position of the femur—specifically the condyles—on the tibia. The condyles are oval-shaped: the longer side of the condyles touches the tibia when the knee is straight, but as the knee bends, the condyles rotate towards their shorter side, decreasing the contact area between the femur and the tibia, and moving the point of contact between the two bones towards the back of the tibia. (*Id*. at 16–17, 23, 29.) The result is eccentric loading, and if the condyles reach the back edge of the tibial plateau, then the result is posterior edge loading. As the knee flexes, the smaller contact area of the condyles concentrates forces passing between the femur and the tibia onto a smaller surface, increasing the pressure experienced on that smaller surface. (*Id*. at 17, 23, 28.) Not only do the condyles

move backwards, but the outer condyle may lift off from the tibial plateau concentrating all of the force on the inner condyle.[27] (*Id*. at 28.) Dr. Fetto notes that some scientists have studied cultures where high-flexion activities—such as kneeling for prayer—are common daily occurrences, and have found erosion of the posterior edge of the tibial plateau in the natural knee. (Fetto Rep. at 18, 21, 23.) Similarly, retrieval of total knee replacements from patients from these cultures has also shown "significant posterior wear of the polyethylene insert" that sits on top of the metal tray of the tibial component. (*Id*. at 18.) Up to this point, Dr. Fetto's opinions appear well supported by the relevant literature.

From these observations, Dr. Fetto posits "that replacement components experience a similar pattern of loading in high flexion as does the native knee." (*Id*. at 19; *see also id* at 23 ("This same force is experienced by the components after replacement.").) Because the replacement components experience the same posterior loading as the native knee, Dr. Fetto continues, "such eccentric loading of the tibia and femoral component can lead to excessive eccentric pressures and debonding of the arthroplasty components from the underlying bone," causing failure of the entire component. (Fetto Rep. at 19.) He provides a slightly more detailed description of this theory later in his report:

> [A]s a compressive load increases in the posterior half of the [tibial] plateau, there will be a counter tensile load on the anterior surface of the knee. Another example of eccentric loading with knee flexion occurs when the lateral condyle lifts off from the tibial articular surface, creating an asymmetrical medial and lateral load. The consequence of either the asymmetric anterior and posterior or medial and lateral loading is that the design is stressed and subjected to potential failure due to tensile loading on the anterior surface or medial surface of the joint. Likewise, there is possible failure due to excessive compression loading on the posterior and/or medial surfaces of the joint; both of which can lead to aseptic failure of the components. Similarly, asymmetric loading of the tibia can result in a toggling effect on the posterior surfaces of the femoral component leading to excessive unloading stresses. This unloading causes bone atrophy and resorption leading to eventual aseptic loosening and painful failure of the component.

[27] *See supra*, at 18 n.11.

(Fetto Rep. at 28.) Neither of these descriptions includes citations to supporting data or studies—disappointing, because part of the court's analysis requires a determination "that the expert considered sufficient data to employ the methodology." *Stollings v. Ryobi Technologies, Inc.*, 725 F.3d 753, 766 (7th Cir. 2013).

Based on his review of the literature and Zimmer's internal documents, Dr. Fetto posits four explanations for the loosening of both femoral and tibial components in high-flex designs as a result of eccentric loading. First, he asserts that the bonds between the component and bones—both femoral and tibial—are susceptible to "tensile loading," that is, forces that pull the bone and component apart from one another. Tensile loading occurs in greater magnitudes in high flexion, he asserts. Next, he asserts that tibial components are more likely to loosen because they have only one plane of contact between the component and the bone, unlike the femoral component, which has multiple planes. Third, he claims that if testing shows lift-off of the polyethylene tray from the tibial baseplate, that lift-off implies that the forces are sufficient to lift the tibial baseplate from the bone as well. Finally, he claims that eccentric loading, combined with the greater forces in high flexion, puts heightened pressure on the femoral component, causing loosening of the femoral component from the bone.

Though analyzing the literature and Zimmer's internal testing is a valid methodology, "an expert must do more than just state that []he is applying a respected methodology; []he must follow through with it." *Brown v. Burlington N. Santa Fe Ry. Co.*, 765 F.3d 765, 773 (7th Cir. 2014). Unlike Dr. Brown, who provided detailed descriptions of the studies he cites, explains why he believes the findings are relevant, and acknowledged limitations in the studies he cited and in his own analysis, Dr. Fetto merely cites a range of studies and Zimmer documents, but he has failed to identify the particular data he used from those studies or the specific Zimmer documents he relied on. Nor has he explained how he applied scientific principles to the underlying data to reach his conclusions. Without that explanation, Dr. Fetto's report reflects

only his "experience and subjective understanding," which "are not reliable scientific evidence," and his opinions regarding loosening of the components must be excluded. *Id.* at 776.

(1) The Bond Between the Bone And Components Has a "Poor Tolerance" to Tensile Loading

The first reason Dr. Fetto gives for his opinion that the femoral and tibial components loosen in deep flexion is that the bonds between the components and the bone—whether cemented or not—have "poor tolerance[s] against tensile loading or rocking movements." (Fetto Rep. at 19.) The court notes ambiguity in this statement: does he mean that the bonds have poor tolerances to tensile loading compared to their tolerances against compressive loading? Or is he stating that the bonds in knee joints have poor tolerance against tensile loading compared to bonds in other joints, which withstand such loading better?

The studies that Dr. Fetto cites and his deposition testimony regarding this aspect of his report provide no insight. He cites three studies—by *Pijls*, *Sharkey*, and *Coughlin*,[28] but does not discuss them in the text of his report, and they do not appear in the record. Zimmer questioned Dr. Fetto about these three studies during his deposition and criticizes them because they are not specific to Zimmer components. (*See* Zimmer Fetto Mem. at 8–9; Fetto Dep. at 260:1–261:18.) Without having reviewed the studies at all, the court observes that the fact that they are not Zimmer-specific is not fatal. More troublesome is Dr. Fetto's failure to explain how these studies form the basis for his opinion that the bonds—both cemented and uncemented—have "poor tolerance[s]" against tensile loading.

When questioned at his deposition about these three studies, Dr. Fetto elaborated that the Coughlin study showed how the anterior or posterior contact points would affect eccentric

[28] (*See* Fetto Rep. at 19 (citing "Pijls BG, Higher revision rate for uncemented total knee arthroplasty - meta-analysis confirming RSA findings. AAOS Annual Meeting, February 16, 2011 - Paper Presentation;" "Sharkey P, Why Are Total Knee Arthroplasties Failing Today? Clin Orthop Relat Res. 2002 Nov;(404):7-13;" and "Coughlin K, Kneeling Kinematics After Total Knee Arthroplasty - Anterior-Posterior Contact Position of a Standard and a High-Flex Tibial Insert Design. The Journal of Arthroplasty, Vol. 22 No. 2 2007").)

loading "and then that would then go ahead and imply a challenge to the fixation." (Fetto Dep. at 260:1–8.) Notably, Dr. Fetto's description suggests that Coughlin addresses the location of the contact point between the femur and tibia; Dr. Fetto does not suggest that the study evaluated how tensile forces varied based on the location of those contact points, or measured the tensile strength of the implant-bone interface. Moreover, Dr. Fetto's statement that the study "impl[ies]" the failure of the implant-bone fixation is unsatisfying. Whether eccentric loading actually does cause debonding or loosens the fixation between the bone and implant is precisely what Dr. Fetto must support with reliable scientific evidence or through the reliable application of scientific principles. At a minimum, Dr. Fetto must explain how the study "implied" the failure of fixation based on basic biomechanical principles.

The second study Dr. Fetto cites, authored by Peter Sharkey, describes, in Dr. Fetto's words, "what were [the most common] modes of failure in arthroplasties." (*Id*. at 260:19–24.) Dr. Sharkey concluded that polyethylene damage is the most prevalent cause of revision, but Dr. Fetto disagrees: in his experience it is "pain and instability and then polyethylene damage," that leads to revision surgery. (*Id*. at 260:25–261:3.) He "think[s] that's also what would be agreed [sic] in the literature." (Fetto Dep. at 260:25–261:3.) Notably, this means that the Sharkey study does not support Dr. Fetto's theory—as discussed above, polyethylene failure does not necessarily suggest loosening of the tibial baseplate from the bone. Second, Dr. Fetto does not identify the "literature" that validates his personal experience that "pain and instability" rather than polyethylene wear are the leading cause of revisions. If the basis for his opinion is simply anecdotal, it has little utility.

The last paper Dr. Fetto cites to support his claim that the bonds—cemented and uncemented—frequently fail when exposed to tensile loading is a study presented by Bart Pijls. Pijls reportedly conducted a meta-analysis of uncemented device failures in an attempt to find trends in the cause of failure. (*Id*. at 261:7–18.) Notably, this study addressed only uncemented devices, and Dr. Fetto has not explained how it applies to his analysis of cemented

devices. Indeed, Dr. Fetto makes no mention of the conclusion of the meta-analysis in either his report or his testimony, and the court is uncertain how it contributed to Dr. Fetto's opinions regarding the "poor tolerances" of the bonds to tensile loading.

Rule 702 does not permit "the district court to choose between . . . two [competing] studies at the gatekeeping stage" or evaluate the quality of an expert's data, inputs, or conclusions. *See Schultz*, 721 F.3d at 433. But where an expert extrapolates from existing data, the court must review the studies and underlying data to ensure the expert reliably reasoned from them. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 144-45 (1997) (conducting detailed review of cited studies and concluding that "[t]he issue was whether these experts' opinions were sufficiently supported by the . . . studies on which they purported to rely. The studies were so dissimilar to the facts presented in this litigation that it was not an abuse of discretion for the District Court to have rejected the experts' reliance on them.") Accordingly, this discussion is not an attempt to quibble with Dr. Fetto's inputs or conclusions, which may in fact find support in the studies. Rather, this discussion is intended to highlight that Dr. Fetto has not enabled the court to even analyze his methodology: he has not sufficiently explained what data is contained within these studies or what reasoning, principles, or methodology he applied to the studies' data and findings. Thus, Dr. Fetto has provided no explanation of how he reached his conclusion that the bond between Flex components and the bones, whether cemented or not, is particularly vulnerable to loosening due to tensile loading or rocking. Failure to sufficiently justify the underlying premise—that the bonds have poor tolerances—is dispositive of the *Daubert* inquiry as it relates to his opinion that the poor tolerances lead to loosening. That opinion will be excluded.

(2) The Tibial Plateau has Fewer Planes to Distribute Stress, Increasing Risk of Loosening

Second, without citations, Dr. Fetto asserts that the tibial component is more prone to loosening than the femoral component "because it has only one flat plane of contact with the

underlying bone," whereas "[t]he femoral component traditionally has a multitude of planes that are in contact with the underlying bone; so these rocking motions and tension stresses are distributed across multiple planes." (Fetto Rep. at 19.) Though the tibial component is more likely to loosen than the femoral component, Dr. Fetto reiterates that the femoral component "planes are also susceptible to early loosening as a result of the stresses and added forces that are present in higher degrees of flexion." (*Id*.) Dr. Fetto provides no citations to explain the basis for his opinion that multiple planes produce a stronger bond, nor does he quantify the increased risk of loosening between the tibial and femoral components. Without any basis for this conclusion, the court is unable to conclude that Dr. Fetto's opinions about the risk of tibial loosening due to one plane of contact are reliable.

(3) Evidence of Polyethylene Lift-Off Shows Tibial Loosening is Likely

Dr. Fetto provides an additional explanation for his opinion that tibial loosening, specifically, is more frequent with high-flex designs: he opines that posterior edge loading "leads to potential for not only failure of the posterior polyethylene but also a compromise of the fixation of the components to the underlying bone due to anterior lift-off force and depression of the posterior aspect of the tibial component into the underlying bone." (*Id.* at 23.) Zimmer's own testing provided evidence of tibial loosening, Dr. Fetto asserts: that testing showed that high-flex designs caused the polyethylene surface, the "tibial insert," to lift off several millimeters from the metal baseplate. Zimmer attempted to correct this problem by adding "a screw to stabilize the tibial insert to the tray," but in Dr. Fetto's view, the screw, also called a "locking mechanism," "only served to transfer the eccentric loading to the implant/bone interface." (*Id.* at 38.) He believes the forces transferred to the implant-bone interface are significant enough to cause the metal tray to separate from the bone because "micromotion only has to occur at dimensions that are far less than that tibial lift-off stress," that is, less than the several millimeters that. as recorded, the polyethylene lifted off the tray. (Fetto Dep. at 273:5–8.) Lift-

off of several millimeters is significant, Dr. Fetto asserts, because, "[a]ny cyclic loading of more than [a few microns, which are a small fraction of a millimeter] inhibits and interferes with the osseointegration of the device and will eventually stress and fatigue and fail the interface. So that's pretty much established dogma among orthopedics." (*Id.* at 273:12–17.) He continues that "it's not a stretch of the imagination to say, hey, if your lift-off tests are causing failure of the locking mechanism . . . and you addressed it, that doesn't mean you've resolved the lift-off problem, it just means you've transferred it to a different point, and you haven't tested it long enough or sufficiently enough to show that it's going to fail at another level." (Fetto Dep. at 273:19–274:3; *see also* Fetto Rep. at 38.) The tests showing the lift-off of the polyethylene were "the most telling" evidence that Zimmer's designs would result in tibial loosening, according to Dr. Fetto, because those tests showed "that as you get into higher degrees of flexion, this [i.e. polyethylene lift-off] was something that didn't occur in the lower degrees of flexion or with the standard testing," and with the addition of the locking mechanism, those forces causing polyethylene lift-off were transferred to the implant-bone interface. (Fetto Dep. at 271:19–23.)

Dr. Fetto's theory is plausible on its face, but his report and testimony reveal no reliable basis for his opinion that the load transferred to the tibial tray, through the screw, was sufficient to cause loosening or micromotion of the tibial component. Plaintiff emphasizes Dr. Fetto's reliance on several peer-reviewed studies that show Flex knees have a higher rate of revision. (Pl. Fetto Resp. at 7.) Those studies—*Han*, *Kang*, and *Namba*—however, either are not specific to tibial loosening or do not discuss the reasons for revisions at all. Those studies do not appear to support Dr. Fetto's specific claim regarding the force transferred to the implant-bone interface. Indeed, at one point in his report, Dr. Fetto appears to recognize that only one study found an increased risk of tibial loosening with high-flex designs:

> Dr. Berger reported an unacceptably high incidence of aseptic loosening he had seen with high flexion non-cemented implants. It had been his experience and opinion that this poses an unacceptably high risk of aseptic failure *for both the*

> *tibia and the femoral components*. He has urged Zimmer to withdraw the CR-Flex Porous design from the market.

(Fetto Rep. at 24) (emphasis added.) Notably, in this passing reference, Dr. Fetto does not provide a citation to Dr. Berger's report and the court is unable to review Dr. Berger's data or evaluate how Dr. Fetto applied Dr. Berger's findings to his analysis.[29] And despite the representation in his report that Dr. Berger found an "unacceptably high incidence" of loosening of tibial components with flex devices, Dr. Fetto admitted in his deposition that he is "not aware of any specific study that relates the failure of a tibia to a flex or a standard device" or of any study that "addresses specifically tibial failure related to a high-flex femoral component." (Fetto Dep. at 266:7–17.) Similarly, Dr. Fetto opines that the force required to lift the poly from the plate would also be sufficient to lift the plate from the bone, but he could not identify any studies that had actually measured the force required to loosen the tibial baseplate from the bone. Rather, "the only studies [Dr. Fetto is] aware of that have actually measured a lift-off stress were focused on the lift-off stress and displacement of the insert," that is, the lift-off of the "tibial articular surface from the baseplate," not the displacement of the tibial baseplate from the bone. (Fetto Dep. at 275: 5–11.) In light of this testimony, the court cannot identify any basis for Dr. Fetto's claim that Dr. Berger reported an "unacceptably high incidence of aseptic loosening . . . for . . . the tibia" components of NexGen Flex knees. (Fetto Rep. at 24.)

Dr. Fetto has not directed the court to any peer-reviewed published literature that supports his opinion that forces causing failure of the polyethylene necessarily cause failure of the stronger bond between metal and bone, even if transferred to the implant-bone interface through a screw. Peer-reviewed literature, of course, is not the only way Dr. Fetto could support

[29] Earlier in that paragraph, Dr. Fetto cited a 2001 study by Berger, entitled "Problems with Cementless Total Knee Arthroplasty at 11 Years Follow Up," which does not appear to address high-flex components specifically. (*See* Fetto Rep. at 24 (citing reference 32).) The court does not believe that this study is the same Berger study referenced by Dr. Fetto in the quoted text above: the study's title is not specific to flex-components and the Flex designs had not been on the market long enough for an 11-year follow up in 2001.

his opinion. An expert need not conduct his or her own testing, and Dr. Fetto is certainly permitted to rely on data collected elsewhere, provided that he reliably explains how the data supports his conclusions. *See NutraSweet Co. v. X-L Engineering Co.*, 227 F.3d 776, 790 (7th Cir. 2000). In his report, Dr. Fetto cites heavily to Zimmer's internal testing (*see* Fetto Rep. at 24, 38–39), but he has not sufficiently explained what data he relied on from those internal tests, what data he disputes, or what methodology he employed to analyze Zimmer's internal testing data.

As he did for his other opinions, Dr. Fetto has cited (without discussing) several documents that are not included in the record,[30] and the court is unable to determine whether these studies provide reliable support for his conclusions. Significantly, the documents that the court has been able to locate do not appear to support Dr. Fetto's conclusions. The court's review suggests that Zimmer did understand that the high-flex design could cause polyethylene damage and potentially lift the polyethylene surface off the baseplate. As Dr. Fetto has

[30] Dr. Fetto cites "Berger RA, Problems with Cementless Total Knee Arthroplasty at 11 Years Follow up Clin Orthop 2001;392:196-207," "Kamath S, Comparison of peri-prosthetic bone density in cemented and uncemented total knee arthroplasty. Acta Orthop Belg. 2008 Jun;74(3):354-9" and "Letter from Dr. Booth to Cheryl Blanchard re anterior femoral resorption 11/11/2009 Z04027116." (Fetto Report at. 23–24.) He also cites "Landy MM, Wear of UHMWPE Component of 90 Retrieved Knee Prostheses J Arthroplasty. 1988;3 Suppl:S73-85." and "Lonner J, Prodromes of failure in total knee arthroplasty. J Arthroplasty. 1999 Jun;14(4):488- 92." (Fetto Rep. at 39.) Though the court has been unable to review the documents, some problems are apparent from the titles alone: Kamath's study apparently addresses bone density, rather than polyethylene wear or tibial loosening. Dr. Booth's letter appears to raise concerns about femoral resorption, rather than tibial loosening due to posterior loading or polyethylene wear. The court remains uncertain how these studies apply to Dr. Fetto's theory of loosening based on posterior edge loading.

The most relevant study appears to be a 1999 study by Jess Lonner. The court was able to access the abstract in its own research. (Jess Lonner, *Prodromes of failure in total knee arthroplasty*, 14 J. Arthroplasty 488 (1999), *available at* http://www.ncbi.nlm.nih.gov/pubmed/10428231 (last visited June 12, 2015).) That study suggests there may be a correlation between polyethylene wear and implant failures: the abstract suggests that in a review of 102 revision total knee arthroplasties 43% showed polyethylene wear and 80% showed complete radiolucencies. (*Id.*) While this might suggest a correlation between polyethylene wear and loosening, the court refuses to infer Dr. Fetto's reasoning from a single citation, when he has included no discussion of the study, its application to this case, or its limitations, in his report.

admitted, "the interface between the polyethylene and the plate was weaker than the plate to the bone," (Fetto Dep. at 272:19—21), and he has not explained what data or methods led him to the conclusion that a force sufficient to lift the polyethylene from the baseplate must also be sufficient to loosen the stronger bond between the bone and the baseplate.

Dr. Fetto first cites document "Z007135," without description or explanation. (Fetto Rep. at 23.) That document is a summary of Zimmer testing of the CR-Flex Knee completed on September 9, 2002. (*See* Zimmer Test Results, Ex. E to Zimmer Reply Mem. in Supp. of Mot. to Exclude Fetto [1494-5], Z7135.) The testing was designed to assess whether the tibial component locking mechanism would resist anterior forces created by posterior edge loading: a femoral component was placed on the tibial component at a flexion angle equal to 155° and loaded with 1735 newtons (a measure of force) for 219,000 cycles, estimating 20 years of use. (*Id.*) The test showed "no disassociation of the inserts from the tibial baseplate" but did show "surface deformation at the point of contact in the form of cold-flow, but no evidence of cracking or fracture on the specimen surfaces, or internally." (*Id.*) That is, the study appears to show polyethylene damage at a posterior contact point, but also shows that the locking mechanism prevented the polyethylene from lifting off the tray. As the court reads these results, the study did not evaluate, let alone conclude, whether the metal tray would loosen from the bone.[31]

Next, Dr. Fetto cites concerns raised by Dr. Harry Rubash, an orthopedic surgeon at Massachusetts General Hospital who was hired by Zimmer to help study the design of the Flex implant during pre-market testing. According to Dr. Fetto, Dr. Rubash was concerned about "the effect of the impingement posteriorly of the femoral component on the tibial component

[31] Dr. Fetto then cites a long list of studies for the proposition that the loss of fixation between the bone and the metal tray "has been clinically expressed as an aseptic loosening and painful failure of the knee component." (Fetto Rep. at 23.) Some of these studies do appear relevant to the questions in this case. For example, Dr. Fetto cites an article by Shiramizu titled "Tibiofemoral contact areas and pressures in six high flexion knees." (*See* Fetto Rep. at 23) (citing reference 26.) Again, however, Dr. Fetto has provided no description of the content of these studies.

leading to accelerated wear and potential failure." (Fetto Rep. at 24.) He points to a 2003 presentation by Dr. Rubash entitled "Robotic Analysis of Knee Kinematics, presentation Harvard Medical School," which the court believes is the presentation labeled Z01542842–Z01542884. (*See* Exs. P-6 to Zimmer Mem. in Supp. of Tibial Loosening Mot. [1310-23]; Ex. P-7 to Zimmer Mem. in Supp. of Tibial Loosening Mot. [1310-24]; Ex. P-8 to Zimmer Mem. in Supp. of Tibial Loosening Mot. [1310-25]; Ex. P-9 to Zimmer Mem. in Supp. of Tibial Loosening Mot. [1310-26]; Ex. P-10 to Zimmer Mem. in Supp. of Tibial Loosening Mot. [1310-27].) Dr. Fetto does not explain which part of this 40-plus-slide presentation he relies on, or how it contributed to his analysis. Dr. Rubash himself concluded that the High Flex CR and the NexGen CR "showed no statistically significant differences . . . in translation" posteriorly of the femoral condyles during flexion up to 150 degrees. (*See* Z01542864, Ex. P-8 to Zimmer Tibial Loosening Mem. [1310-25].) That is, according to Dr. Rubash, the condyles on the flex design did not move significantly further back on the tibial baseplate than the condyles on the standard design, undermining Dr. Fetto's theory that the flex produces greater "posterior loading." A later slide does suggest that "[p]osterior tibial poly edge loading was observed in 3 specimens," of the CR flex design and that "the [anterior-posterior] dimension of the tibial poly component may need to be increased." (Z01542877, Ex. P-10 to Zimmer Tibial Loosening Mem. [1310-27] at 3.) The presentation may support a finding that the back of the polyethylene could be damaged; but the presentation does not appear to establish that posterior edge loading would cause debonding or loosening of the metal tray from the bone.

According to Dr. Fetto, Drs. Kamath and Booth "expressed concerns over anterior lucency under the femoral component; both of which had represented stress shielding[32] of the

[32] "Stress shielding" is not defined in Dr. Fetto's report. The court understands it to be the phenomenon of decreasing bone density, or weakening of the bone, when normal loads are removed from the bone, that is, when a bone experiences less load than is typical. (*See e.g.* Dr. Wright Expert Report, Ex. M. to Pl.'s Mem. in Resp. to Mot. for Summ. J [1464-13], 35.)

distal femur due to excessive eccentric loading of the posterior aspect of the femur in high degrees of flexion." (Fetto Rep. at 24.) Though the court is, again, unable to locate the two documents cited, Dr. Fetto's own description reveal that these concerns relate to a mechanism of femoral, not tibial, loosening.

Dr. Fetto also claims that Drs. Bertin and Walker warned Zimmer that "asymmetric and significant increase in the posterior tibial loading may cause excessive damage to the tibial polyethylene insert and potential lift-off anteriorly of the insert/tray from the tibia." (Fetto Rep. at 38.) Though Dr. Fetto states that the "insert/tray" could lift off from the tibia, he has not produced any documentation that shows concerns about anything other than polyethylene.[33] Dr. Fetto suggests that concerns about the lift-off of the tray were "noted to Zimmer by Prof. Peter Walker (1/27/2001 (Z015279), 5/13/2002 (Z014363), and 6/30/2002 (Z014325)), and internal documents (Z004638, Z007135/6, Z006293, Z006323, Z006542, Z006627, Z007147, Z007149, Z007177/8)." (Fetto Rep. at 38–39.) Again, this assertion is impossible to assess because Dr. Fetto has done no more than list a string of documents: he has not described the content of these documents, nor has he identified what data he relied on, which data he may have discounted as unreliable, or which, if any, conclusions he agreed with or disputed. This cursory analysis does not satisfy Rule 702, which requires that an expert "explain the methodologies and principles supporting the opinion." *Minix v. Canarecci*, 597 F.3d 824, 835 (7th Cir. 2010). Dr. Fetto's willingness to rely on these test results without comment is troubling, particularly in light of his opinion that Zimmer's own testing was suspect. (Fetto Rep. at 39) ("Zimmer's test variation with clinical observations undermines the validity of Zimmer's testing methodology.")

[33] As noted above, some of Zimmer's testing, specifically the Z007135 and the studies by Rubash and Li, did reveal the possibility of posterior edge loading and polyethylene damage at a posterior contact point.

Zimmer highlights other reasons to doubt Dr. Fetto's methodology, and the court shares those concerns, as well. In one of the few instances where Dr. Fetto discusses the content of Zimmer's internal testing, he cites a test which, he states, showed that the Flex design "demonstrates a 35% increase in posterior contact loading with a 'high-flexion' component." (Fetto Rep. at 38.) Zimmer has correctly noted that the document that Dr. Fetto cites, in fact, states that there was a 35% increase in contact loading *area*, which would in fact decrease contact loading pressure. (Zimmer Reply Brief [1494], at 11.) Plaintiff responds that this was simply a typo in Dr. Fetto's report, but the context suggests otherwise: the statement appears in a paragraph in which Dr. Fetto criticizes Zimmer for continuing to market the high-flex designs despite being aware that increased posterior edge loading was likely based on its internal tests. Dr. Fetto's apparent misinterpretation of the 35% figure undermines his credibility and illustrates the need for experts to identify and describe the data they rely on to enable the court to assess their methodology.

Finally, Dr. Fetto explains that Zimmer's consultants "demonstrated that in higher degrees of flexion, there were similar consequences encountered [with the CR design] as seen with the PS designs," including "excessive compression on the posterior aspect of [the] tibial plateau," and the femoral component "dig[ging] into" the polyethylene tibial plateau, causing deformation and excessive wear of the poly. (Fetto Rep. at 39.) According to Dr. Fetto, "these observations," presumably referring to the damage to the poly, "were documented in patients who's [sic] devices had failed over time and demonstrated excessive polyethylene wear on the posterior aspect of the components." (Fetto Rep. at 39.) He cites three studies—by *Cho*, *Landy*, and *Lonner*—in support. (*Id.*) As the court understands this argument, Dr. Fetto contends that because polyethylene wear has been observed in failed devices, testing that reveals a likelihood of polyethylene wear should have suggested to Zimmer that their device would likely fail. Again, this conclusion is not obviously supported by the studies Dr. Fetto cites. The study by Cho, for instance, does not discuss polyethylene wear of the tibial component or

anterior lift-off of the poly; it focuses on loosening of the *femoral* components and hypothesizes that edge loading could result in stresses at the posterior femoral condyle. (Cho et al, *Three- to six-year follow-up results after high-flexion total knee arthroplasty: can we allow passive deep knee bending*? Knee Surg. Sports Traumatol. Arthosc. (July 29, 2010), Ex. D to Rusch Aff. [1454-4].) The studies by Landy and Lonner did not appear in the record, nor are they discussed in the text of Dr. Fetto's report.

Dr. Fetto has failed to identify for the court a basis in either peer-reviewed studies or data from Zimmer's internal testing for his opinions that forces sufficient to lift the poly from the metal tray are also sufficient to lift the tray from the bone. This might be explained in part by Dr. Fetto's consideration of sources not described in his report, including informal conversations. He explained that his "experience and . . . knowledge comes from conversations with my peers, such as Dr. Norman Scott, one of the designers of NexGen. He explained to me that tibial failures are the more common failure among this device. His experience is that this is probably due to eccentric loading, and has offered his opinion and suggestions . . . that the points of contact should be changed. So I relied on the experience of the designer to tell me what he thought." (Fetto Dep. at 267:1–12.) Dr. Fetto nevertheless insists stated that he did not actually rely on the conversation; it was merely "one piece of information that I thought was consistent with my impression across tibial failures." (*Id*. at 267:13–17.) Dr. Fetto refers to Dr. Scott a second time, as well, however, pointing out that Dr. Fetto's "hypothesis" of micromotion and "seesawing" of the tibial component "is exactly the way Dr. Scott has described it both in lectures and to me personally." (*Id*. at 317:19–318:2.)

The possibility of polyethylene damage from high-flexion devices does appear to be supported by literature and internal testing that Dr. Fetto cites. To pass *Daubert* muster, however, Dr. Fetto must also explain the reasoning and data underlying his opinion that polyethylene damage either causes, or is evidence of, loosening. Dr. Fetto has not provided such an explanation, and the court is troubled by several aspects of his reasoning. In his expert

report, he referenced, but did not cite, a report in which Dr. Berger purportedly found "unacceptably" high risks of tibial loosening with flex-components, but when asked at his deposition whether he knew of any studies that correlated tibial failures with flex components, he could identify none. Finally, his deposition testimony suggests that Dr. Fetto himself inferred or implied, without support in data or literature, the critical step in his analysis: that forces sufficient to lift the polyethylene from the tray are necessarily sufficient to lift the tibial tray from the bone.

This reasoning is insufficient. In *Hartman v. EBSCO Industries*, the Seventh Circuit upheld a district court's decision to exclude an expert who

> did not perform any kind of testing . . . introduced no evidence that his theory had been subjected to peer review or publication, or has been generally accepted . . . did not discuss the known or potential error rate of his theory . . . instead stating only that the product defect 'is easily foreseeable especially during the design process and this problem should have been addressed . . . in the developmental stage.'

758 F.3d 810, 818 (7th Cir. 2014). Dr. Fetto's opinions regarding the risks of tibial loosening mirror those by the expert in *Hartman*. It may have been apparent to Dr. Fetto that the designs would cause tibial loosening, but he has presented no evidence that other scientists would accept this theory and the court cannot otherwise ensure that Dr. Fetto's opinions regarding tibial loosening are adequately reliable.

(4) Posterior Edge Loading Can Cause Femoral Loosening

Dr. Fetto also opines that posterior edge loading can cause loosening of the femoral component. Dr. Fetto asserts that "increased loading with increasing degrees of flexion would result in a potential rocking effect on the femoral component, leading to aseptic failure and compromise of implant fixation." (Fetto Rep. at 40.) He opines that the device would be more prone to loosening when "combined with non-cemented surgical techniques" because the combination "was especially vulnerable to aseptic failure due to micro-motion of the bone-implant interface inhibiting osseous integration to the host bone." (Fetto Rep. at 40.) He

asserts further, that "Zimmer's 'high-flex' implants, by removing more posterior bone exposed weaker posterior cancellous condylar bone to excessive loads, thus potentially creating a rocking effect on the femoral component." (*Id.*) Dr. Fetto does cite several studies that appear relevant, but his report presents only his conclusions without any description of how he arrived at them.

The Seventh Circuit has made clear that the district court's role is not to evaluate "the ultimate correctness of the expert's conclusions," but rather "the soundness and care with which the expert arrived at her opinion." to *Schultz*, 721 F.3d at 431. The court's focus is, thus, "solely on principles and methodology, not on the conclusions they generate.'" *Id.* (quoting *Daubert*, 509 U.S. at 595)). Whether Plaintiff in fact has other evidence to support Dr. Fetto's conclusions (or whether Zimmer's experts themselves agree with some of Dr. Fetto's opinions) does not bear on whether Dr. Fetto reached his conclusions in a reliable and careful manner. In the court's view, he has not: Dr. Fetto does not describe how or why the cementless interface is more prone to loosening. Nor does he describe the clinical evidence that he cites or explain why he finds it persuasive. Similarly, he fails to explain—beyond merely declaring—why exposure to cancellous bone "potentially creat[es] a rocking effect on the femoral component." (*Id.*) As the court has no assurances that Dr. Fetto followed a valid methodology when reaching his opinions, he is not permitted to testify regarding femoral loosening.

b. Dr. Fetto's Criticism That Zimmer's Posterior Stabilized "PS") Design Causes Increased Posterior EdgeLoading Is Not Reliable

After concluding that posterior loading increases the risk of aseptic loosening, Dr. Fetto opines that Zimmer's Posterior Stabilized ("PS") design, which calls for placement of the tibial post in the center of the tibial plateau, "forced loading onto the posterior half of the tibial plateau." (Fetto Rep. at 40.) He states that the post

> created, at higher degrees of flexion, a seesaw effect to simultaneously occur on the tibial and femoral components. The consequence of this eccentric loading of the tibial plateau is anterior lift-off and/or posterior depression of the tibial

> component into the underlying bone. Together with decrease in posterior femoral bone this eccentric loading of the components will inevitably lead to excessive motion between the components and the underlying bone. This is a particular concern in the noncemented version of the "high-flexion" components. Noncemented components cannot tolerate the occurrence of micro-motion as it will prevent integration and long-term fixation of the implant to the host bone.

(Fetto Rep. at 40.) Dr. Fetto again repeated the claim that there have been "a significant number of reports of aseptic failures of both tibial and femoral components in the cemented and non-cemented versions of high-flexion devices extending across NexGen Gender Specific and LPS family of implants." (Fetto Rep. at 41–42.) Dr. Fetto cites 13 studies in support of that claim,[34] but, as described above, when questioned at his deposition he stated that he did not know "of any specific study that addresses specifically tibial failure related to a high-flex femoral component." (Fetto Dep. at 266:15–17.) The court, therefore, does not understand how Dr. Fetto reached his conclusion that there have been "significant" reports of tibial loosening with Zimmer NexGen products. Nor does the court understand how, even if there are significant reports of tibial loosening with LPS designs, those reports show that the location of the post is the cause of the failures.

Even more befuddling is Dr. Fetto's assertion that "[s]imilar clinical results [that is, tibial and femoral loosening] were reported by those surgeons who wish to employ cruciate-retaining devices. Unfortunately CR as well as PS high-flexion devices have suffered from similar modes of failure and reports of aseptic loosening." (Fetto Rep. at 42.) The court does not follow Dr. Fetto's reasoning. He provides no citations to those studies showing the "similar clinical results"

[34] Yet again Dr. Fetto has provided no additional information about these studies. The court does not know whether these studies address tibial or femoral loosening, whether they discuss only Zimmer high-flex designs or include other manufacturer's devices, how many patients each study followed, or what percentage of those patients suffered failure. That is, Dr. Fetto has presented only his bottom-line conclusion, without describing the data he relied on or factual underpinnings for that conclusion. While employing experience to analyze data assembled by others is a valid methodology, *Phillips v. Raymond Corp.,* 364 F. Supp. 2d 730, 743 (N.D. Ill. 2005), conclusions alone, without the bases for those conclusions, are inadmissible. *Wendler & Ezra, P.C. v. Am. Int'l Grp., Inc.*, 521 F.3d 790, 791 (7th Cir. 2008).

for CR devices. In any event, Dr. Fetto's specific criticism of Zimmer's PS design is that the location of the post exacerbated posterior loading by preventing a more centered contact point between the tibia and the femur. The CR design, however, does not include a post and cam mechanism at all, but relies instead on the posterior cruciate ligament to stabilize the knee. If Dr. Fetto believes that the CR devices, which lack a post, show similar rates of loosening, that evidence cannot support an opinion that the location of the post is the cause of that failure or exacerbates posterior loading. The court perceives no reliable methodology supporting Dr. Fetto's opinion that the location of the post is the cause of tibial loosening.

Dr. Fetto opines that placing the post further forward on the tibial tray would provide a safer alternative design because the post would stay engaged past 135 degrees of flexion. (Fetto Rep. at 34–35.) Dr. Fetto included a drawing in the report to show how he thinks the alternative design would operate. Zimmer argues that Dr. Fetto's proposed alternative design is not based on "any definitive science" suggesting that it is in fact safer, or that it was feasible at the time of Ms. Batty's surgeries. The court agrees. The drawings Dr. Fetto presented are based on his sketches of components, which Dr. Fetto held in his "hand and . . . watch[ed] them move as they're attached to . . . bony elements." An artist "perfected [Dr. Fetto's sketches] into something that was a little bit more presentable." (Fetto Dep. at 287:4–25.) The drawings of the safer design are a "simplified analysis" based on his "visual observation;" they are not based on any testing such as FEA models, fluoroscopy, or a clinical study of the components in patients. (*Id*. at 288:1–15; 319:9–22.) The court concludes that the alternative design drawings are based on nothing more than Dr. Fetto's own conceptual drawings: these are simply not scientifically reliable.

* * *

In sum, Dr. Fetto has not sufficiently explained how he reached the conclusion that Zimmer's designs cause aseptic loosening of the tibial component. As part of its "gatekeeping role" as described in *Daubert*, 509 U.S. at 597, the court is required to ascertain whether the

expert arrived at his or her opinion through reliable methods. Without descriptions, or even copies, of those studies and tests he considered, the court is left with only Dr. Fetto's conclusions: "[a]n expert who supplies nothing but a bottom line supplies nothing of value to the judicial process." *Wendler & Ezra, P.C. v. Am. Int'l Grp., Inc.*, 521 F.3d 790, 791 (7th Cir. 2008). Moreover, Dr. Fetto repeatedly cites Zimmer's internal testing as the basis for his opinions, without explanation or qualification, while simultaneously criticizing the adequacy of those tests. Dr. Fetto may have cited studies that answer some of the questions the court raises here, and Plaintiffs may be able to present evidence that fills in gaps left open by Dr. Fetto, but he has failed to connect the dots in a way that enables the court to adequately examine the bases for his conclusions and conduct a reliability analysis. Dr. Fetto's opinions regarding the risk of loosening are excluded.

3. Dr. Fetto's Opinions That Zimmer's Testing Was Inadequate

Dr. Fetto also opines that Zimmer's testing protocols were inadequate. He contends that because high flexion knees attempted to provide new ranges of motion and clinical benefits, Zimmer should have been exceedingly cautious:

> Roughly 80% to 85% of all knee arthroplasties are performed by surgeons who average 25 of these types of surgery per year (76, Tria Dep., pg 102, Ex. 527 to Tria Dep.). These facts are important when designing implants with a promise to achieve and accommodate extremes of function. The testing that needs to be done to assure safety of these implants in high-flexion activities, for example, should assume worst case scenarios taking into account all forces affecting the knee from the foot to the hip. No compromise or assumptions should be made concerning the implant's ability to accommodate such conditions, in this case "high flexion." The most important point is to not assume that a new implant design can provide the same margin of safety that predicate implants have provided under lesser degrees of functional motion. It should be noted that high flexion is a new area of endeavor and cannot be predicated on previous designs as previous designs have been shown to not perform or provide high degrees of flexion and therefore should not be used as an assumption of what would happen in high-flexion environments.

(Fetto Rep. at 22.) Plaintiff argues that Dr. Fetto's opinion was "based on his clinical experience, experience as a design surgeon who has tested new designs and studies that have looked at the kinematics of the knee in high flexion," and that he "went through the same testing

analysis that he has used on his own designs." (Pl. Fetto Resp. at 18–19.) Even if Dr. Fetto is qualified to testify regarding appropriate testing, the court can discern no methodology or standards underlying his analysis. Rather, it appears that Dr. Fetto is merely providing his unsupported personal opinion that innovative technologies should undergo more rigorous testing before being marketed. Assuming that Dr. Fetto did apply some (unidentified) standards, he has failed to describe how he arrived at this conclusion: He notes that Zimmer should have conducted "well-controlled clinical studies" and "much more elaborate FEA and bench testing with force assumption circumstances covering much wider parameters." (Fetto Rep. at 22.) He does not, however, describe what parameters Zimmer used in its FEA analysis, why those parameters were inadequate, how those inadequate parameters influenced the test results, what proper parameters should have been included, or what that hypothetical proper testing would have disclosed. Dr. Fetto's opinions regarding testing must be excluded.

4. Dr. Fetto's Opinions on Warnings

Dr. Fetto opines that Zimmer did not adequately warn about the risks associated with high flexion activities. He asserts that "Zimmer failed to warn both surgeons and patients of the attendant risks which were disproportionately greater than the theoretical benefits the high flexion . . . devices were to provide." (Fetto Rep. at 5; *see id.* at 37) ("[T]o promote a theoretical 'benefit' that in fact poses a disproportionate risk of an adverse outcome is a 'failure to warn' on Zimmer's part.") Once again, the court can identify no methodology to support Dr. Fetto's opinion. Dr. Fetto has not even described what warnings were in fact included in Zimmer's package insert or why he believed those warnings were inadequate. Nor did he describe what an adequate warning would have included.

Dr. Fetto's testimony casts further doubt on his methods.[35] He testified that he has "no specific criticism of the standard warnings, but I haven't read [the package inserts] to make a

[35] In his deposition Dr. Fetto also testified as follows:

(continued . . .)

comment." (Fetto Dep. at 146:22–147:1.) Moreover, while he is generally "familiar" with Zimmer's prescribed surgical technique—the document in which Zimmer provides surgeons with step-by-step instructions for implantation—he did not review the surgical technique for his work in this case. (Fetto Dep. at 146:14–21.) He testified that "I'm not certain why their technique is as it is, but I have no criticism of it." (Fetto Dep. at 147:7–8.) Plaintiff responds by highlighting Dr. Fetto's testimony that, in the documents he reviewed in this case, he did not see any warnings about an increased risk of loosening when the flex is used over 120 degrees. (Fetto Dep. at 479:1–11.) If Dr. Fetto did not review the relevant package inserts, his opinions regarding the adequacy of Zimmer's warnings cannot be reliable.

Zimmer's motion to exclude the testimony of Dr. Fetto is, accordingly, denied with respect to his rebuttal report to Dr. D'Lima, but granted with respect to his opinions regarding the risks of loosening, the adequacy of Zimmer's testing, and the adequacy of Zimmer's warnings.

Q. Have you had a chance to look at Zimmer's package inserts for the flex products and the 5950 tibial product?
A. No.
Q. In the course of your work in this case, have you looked at them at all?
A. No.

(Fetto Dep. at 146:3–9.) He amended his testimony to read:

Q. Have you had a chance to look at Zimmer's package inserts for the flex products and the 5950 tibial product?
A. No, not in preparation for this deposition but I saw it previously
Q. In the course of your work in this case, have you looked at them at all?
A. Yes.

(Fetto Errata Sheet, Ex. B to Decl. of Ronca [1458-2].)

IV. Motions for Summary Judgment[36]

The court will grant a motion for summary judgment when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). The court "construe[s] all facts and draw[s] reasonable inferences in the light most favorable to the nonmoving party." *Righi v. SMC Corp.*, 632 F.3d 404, 408 (7th Cir. 2011). The court will grant summary judgment against a party that does not produce evidence that would allow a reasonable jury to find in its favor on a material question. *McGrath v. Gillis*, 44 F.3d 567, 569 (7th Cir. 1995). As a corollary, if the only evidence offered to support an element of a plaintiff's claim is expert testimony and such testimony is inadmissible under *Daubert*, summary judgment must be granted. *See Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 905 (7th Cir. 2007). The parties agree that Pennsylvania law applies to Batty's claims because that is where her surgery (and alleged injury) occurred. (Zimmer SOF in Supp. of Mult. Grounds Mot. ¶ 2); *Cf. Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 865 (7th Cir. 2010).

Zimmer moves for summary judgment on all of Batty's "non-negligence-based product liability claims because Pennsylvania law does not permit such claims." (*See* Zimmer Mem. in Supp. of Mot. for Sum. Judg. on Mult. Grounds [1308], hereinafter "Mult. Grounds Mem.," 2.) Plaintiff Batty has withdrawn her claims of manufacturing defect, breach of express warranty, unjust enrichment, and violations of the Pennsylvania Consumer Protection statute, but continues to press "her strict liability design defect, negligent design defect, and negligent failure

[36] The parties have filed numerous motions related to the other bellwether plaintiffs, Ramona Diano and Randy Pudwill. (*See* Individual Dockets, Nos. 12-cv-3554 and No. 11-cv-4489.) By agreement, arguments and motions that do not affect Plaintiff Kathy Batty's case are deferred. (*See* March 10, 2015 Order [1433], ¶ 3 ("As Batty has been selected for the first trial, further briefing on the *Daubert* motions on the Kurtz, Ochoa and Kantor witnesses is stayed, as is briefing on Plaintiffs' Motion to Exclude Cumulative Testimony. . . . Likewise, any arguments and/or motions pertaining to Diano and/or Pudwill in the pending Motions for Summary Judgment will be stayed and will not be the subject of further briefing at this time.").)

to warn claims." (Pl. Resp. to Mult. Grounds Mem. [1465], hereinafter "Mult. Grounds Resp.," 1.) In addition, while Plaintiff has not expressly waived her breach of implied warranty claim, she failed to respond to Zimmer's arguments against it (*see* Mult. Grounds Mem. at 12–13), and summary judgment is appropriately granted to Zimmer on this claim, as well. *See Bonte v. U.S. Bank*, N.A., 624 F.3d 461, 466 (7th Cir. 2010) ("Failure to respond to an argument . . . results in waiver."); *cf. Arendt v. Vetta Sports, Inc.*, 99 F.3d 231, 237 (7th Cir. 1996) ("Because [plaintiff] did not raise this argument before the district court in response to the summary judgment motion, she has waived this argument.")

For the reasons discussed below, Zimmer's motion [1306] is granted in part and denied in part. The court agrees with Zimmer that the Supreme Court of Pennsylvania, if presented with the issue, would dismiss Plaintiff's strict liability claim, and summary judgment is granted as it relates to this claim. Summary judgment is denied, however, on Plaintiff's negligence-based claim. Material fact questions remain concerning whether Zimmer exercised reasonable care designing its NexGen Flex knee, drafting warnings to accompany the device, and other conduct associated with monitoring the device after it was placed on the market.

A. Pennsylvania Strict Products Liability

In *Hahn v. Richter*, 673 A.2d 888 (Pa. 1996), the Supreme Court of Pennsylvania held that negligence "is the only recognized basis for recovery" against a prescription drug manufacturer where the adequacy of the warnings is at issue. *Id.* at 889. In *Hahn*, the plaintiff suffered injuries after receiving spinal injections of Depo-Medrol, a pain medication. *Id.* at 889. The plaintiff settled with the treating physician but proceeded to trial against the drug manufacturer; the jury found in favor of the manufacturer. *Id.* On appeal, the plaintiff argued that the jury should have received an instruction on strict liability, but the Pennsylvania Supreme Court disagreed. *Hahn*, 673 A.2d at 889. Specifically, the Court cited comment k to the Restatement (Second) of Torts § 402A, which addresses "unavoidably unsafe products," that is, "products that, in the present state of human knowledge, are quite incapable of being made safe

for their intended and ordinary use." The comment explains that such products, "properly prepared, and accompanied by proper directions and warning," are neither defective nor unreasonably dangerous. *Id.* *Hahn* recognized that comment k "denies application of strict liability to products such as prescription drugs, which although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings." *Hahn*, 673 A.2d at 890. *Hahn* ultimately held that "where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability." *Id.* at 891.[37]

Neither *Hahn* nor comment k discusses whether medical devices should similarly be exempt from strict products liability claims, and the Supreme Court of Pennsylvania has not addressed the question. Lower Pennsylvania courts and numerous United States District Courts applying Pennsylvania law have, however, extended *Hahn* in this manner. *See, e.g.*, *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006); *Horsmon v. Zimmer Holdings, Inc.*, No. 11-cv-1050, 2011 WL 5509420, *2 (W.D. Pa. Nov. 10, 2011); *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 749–50 (E.D. Pa. 2007) (collecting several federal court cases applying Pennsylvania law that have extended *Hahn* to medical devices, and doing same). While the depth of analysis in these opinions varies, the overarching rationale is that prescription medical devices, like prescription drugs, present "a unique set of risks and benefits that may be harmful to one person but beneficial to another," such that comment k should apply to bar strict liability claims for injuries arising from prescription medical devices. *See, e.g.*,

[37] *Hahn* does not discuss whether its holding applies to strict liability design defect claims as well. The Court does endorse comment k, which states that so long as a proper warning accompanies a drug, the drug itself "is not defective" in a strict liability sense—suggesting that strict liability design defect claims are not viable either. But as discussed below, the Pennsylvania Supreme Court has elsewhere held that negligent products liability claims remain available for plaintiffs in pharmaceutical products liability contexts, even claims premised on a design defect theory. *See generally Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014).

Soufflas, 474 F.Supp.2d at 749 (citing *Taylor v. Danek Medical, Inc.*, 1998 WL 962062, *7 (E.D. Pa. Dec. 29, 1998)). Further, comment k's language itself suggests medical devices fall within its ambit, explaining that the rule applies to "other drugs, vaccines, *and the like*, many of which . . . cannot legally be sold except to physicians, or under the prescription of a physician." Comment k to § 402A of Restatement (Second); *cf. Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 747 (W.D. Pa. 2004). The court agrees with the reasoning in these cases and concludes that, if presented with the issue, the Pennsylvania Supreme Court would extend comment k to apply to medical devices and therefore exempt medical devices from strict liability claims.

Plaintiff's citations to recent Pennsylvania Supreme Court cases do not sway the court. For instance, Plaintiff cites *Tincher v. Omega Flex, Inc.*, 104 A.3d 328 (Pa. 2014), arguing it stands for the proposition that, notwithstanding *Hahn*, "strict liability claims based on a medical device such as Zimmer's NexGen knee are viable." (Mult. Grounds Resp. at 2.) This is so, Plaintiff explains, because the court in *Tincher* held that "the presumption is that strict liability may be available with respect to any product, provided that the evidence is sufficient to prove a defect." *Id.* at 382. *Tincher* acknowledged *Hahn*'s holding that strict liability is unavailable for prescription drug claims premised on defective design or inadequate warning, *see id.*, but the Court declined to categorically bar strict liability claims for any other types of products, even "innovative products with no comparable alternative design[.]" *Id.* at 396. Plaintiff links this "innovative products" language to medical devices, arguing that medical devices do not deserve the categorical exemption from strict liability that applies to prescription drugs. (Mult. Grounds Resp. at 5–6.)

Plaintiff's argument has some force, but the court is unwilling to read *Tincher*'s tea leaves so expansively absent more explicit language from Pennsylvania's highest court cabining *Hahn* to prescription drugs only. Tellingly, the product at issue in *Tincher* was stainless steel tubing used for natural-gas connections in a home, not a prescription drug or medical device.

See Tincher, 104 A.3d at 336. *Tincher* clarified the standard for imposing strict liability on any products *besides* prescription drugs, but its analysis reaches prescription medical devices only if the reference to "innovative products" includes them. The court does not believe *Tincher*, a lengthy opinion that exhaustively details the state of products liability law in Pennsylvania, intended its presumption in favor of strict liability to apply to prescription medical devices, especially when such devices, as discussed above, share so many similarities with prescription drugs. And, in the only Pennsylvania state appellate court decision to squarely address the issue, that court concluded, albeit with limited discussion, that there is "no reason why the same rational [sic] applicable to prescription drugs [in comment k or *Hahn*] may not be applied to medical devices." *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006). Plaintiff argues that *Creazzo* is not persuasive in light of *Tincher* (Resp. to Mult. Grounds Mem. at 3 n.1), but does not elaborate aside from its argument about medical devices being "innovative products." Absent further guidance from the Pennsylvania Supreme Court, this court concludes that Plaintiff may not proceed on her strict liability claim against Zimmer.

Lance v. Wyeth, 85 A.3d 434 (Pa. 2014) also does not change the court's conclusion. There, the plaintiff brought negligence claims against a drug manufacturer, alleging that the manufacturer unreasonably marketed a drug that was "too harmful to be used by anyone." *Id.* at 461; *see also id.* at 450. The Court rejected the pharmaceutical company's argument that, in a negligence context, Pennsylvania only recognizes manufacturing defects or failure to warn claims. Instead, the court held that "[a] company which is responsible for tendering into the market a drug which it knows or should know is so dangerous that it should not be taken by anyone can be said to have violated its duty of care either in design or marketing." *Id.* at 458. *Lance*'s recognition that negligent design claims are available in a pharmaceutical products liability case does nothing to upset *Hahn*'s rule precluding strict liability claims against pharmaceutical drug manufacturers. Indeed, the *Lance* court noted Pennsylvania's "refusal to extend strict liability to prescription drug manufacturers, consistent with the treatment for

'unavoidably unsafe products' reflected in comment k to Section 402A," and observed that Pennsylvania uses a "blanket approach applying comment k to preclude strict-liability design-defect claims for all prescription drugs." *Lance*, 85 A.3d at 442 n.11; (Mult. Grounds Reply at 5.) This court concludes that Plaintiff Batty may bring negligence claims predicated on failure to warn, design defect, or other negligence-based theories, but she cannot bring strict liability claims against Zimmer. *Cf. Lance v. Wyeth*, 85 A.3d 434, 461 (Pa. 2014) (to prove negligent design defect, Plaintiff must show that Zimmer violated its duty of care by introducing a product "into the marketplace, or continu[ing] a previous tender, with actual or constructive knowledge that the [knee implant] is too harmful to be used by anyone" who sought to achieve the high flexion the NexGen Flex implants promised).

Plaintiff's other arguments fare no better. She contends that the "blanket approach to immunizing prescription drug manufacturers from strict liability recognizes that because prescription drugs are subjected to extensive scrutiny before reaching consumers, there is less need to protect consumers by imposing strict liability," and that this is not true for medical devices. (Mult. Grounds Resp. at 6–7.) To the contrary, as Zimmer points out, certain medical devices do not go through the 510(k) approval process—but rather through the FDA's pre-market approval process, which involves the same level of scrutiny and testing that prescription drugs must undergo before such drugs are allowed into the marketplace. (Mult. Grounds Reply at 6 (citing 21 C.F.R. § 814).) Conversely, certain generic prescription drugs are allowed to be sold even though they do not go through the FDA's pre-market approval process, and these drugs retain their exemption from strict liability under *Hahn*. Simply put, Plaintiff's arguments about the level of regulatory scrutiny brought to bear on drugs and medical devices do not satisfy the court that they fare differently under comment k of the Second Restatement.

Plaintiff also cites extensively to the deposition testimony of Dr. Robert Booth, Zimmer's lead design surgeon for the Gender knee who also uses such devices in his practice. (*See* Mult. Grounds Resp. at 7–9.) Dr. Booth testified that he makes a decision about which device

to place into a person's body prior to surgery. (*See id.* at 8.) Plaintiff seizes on this testimony, arguing that it shows that "when it comes to medical devices, the physician does not make a conclusion as to the case-specific risks and benefits," in contrast to drug prescribing decisions. (*Id.* at 9.) The court sees less significance in Dr. Booth's testimony, which establishes the unsurprising fact that Dr. Booth prefers to use certain replacement devices based on his expertise and knowledge about the biomechanics of the knee. As Zimmer rightly points out, "[t]his is the same as a doctor prescribing a prescription drug, who may have an opinion in advance of meeting with a patient concerning what drug to prescribe for a particular medication[.]" (Mult. Grounds Reply at 8.) Rather than evincing a blind prescribing decision concerning what knee replacement to use, Dr. Booth explained that, while he has his preferences, he still has a conference with his patient in advance of the surgery that helps him decide which prosthesis is appropriate. (*See* Mult. Grounds Resp. at 8.) In short, Plaintiff's arguments fail to convince the court that strict liability should attach to medical devices and not prescription drugs.

B. Negligent Design Claims

Zimmer urges the court to grant summary judgment on Ms. Batty's negligent design defect claims related to the femoral component. (Zimmer's Mot. for Summ. J. and Partial Summ. J. [1317].) Before delving into the specifics of Ms. Batty's claim, the court pauses to discuss Pennsylvania's products liability law.

To prove a negligent products liability claim under Pennsylvania law, a plaintiff must establish the traditional tort elements, namely that "(1) the manufacturer owned [sic] a duty to the plaintiff, (2) the duty was breached and (3) such a breach was the proximate cause of plaintiff's injuries." *Soufflas*, 474 F. Supp. 2d at 753. In *Lance*, the court distinguished strict liability and negligence claims: the strict liability inquiry focuses "solely" on the condition of the product, while there is "greater flexibility" in presenting negligence claims, "where the *conduct* of manufacturers and/or suppliers is squarely at issue." *Lance*, 85 A.3d at 458 (emphasis in

original). *Lance* teaches that "in the negligence arena at least, the substantive allegations are more important than the labels." *Id*. Though the appeal was from a grant of summary judgment, the Pennsylvania high court recognized that the issue was a challenge to plaintiffs' pleadings. Plaintiffs had alleged that the defendant drug manufacturer violated its duty of "due care in tendering into the marketplace a product whose dangers are known (or should be known) to outweigh its benefits." *Lance*, 85 A.3d at 455 n.27. The court concluded that plaintiff's claims, if proven at trial, would "manifest[] a failure of '*vigilance* commensurate with the harm which would be likely to result from relaxing it." *Id.* (quoting *Incollingo v. Ewing*, 282 A.2d 206, 219 (Pa. 1971)) (emphasis in original).

Lance refrained from laying out specific elements that must be established to prove negligence in a products liability case, but the court identified a "continuum" that moves from "a warning of dangers, through a stronger warning if justified by the known risks, through non-marketing or discontinuance of marketing when it becomes or should become known that the product simply should not be used in light of its relative risks." *Id.* at 459–60. The court concluded that this "entire continuum is within the scope of the general framework of the applicable duty of care." *Id.* at 459–60. Thus, in a products liability case, Pennsylvania courts do not appear to recognize sharp distinctions between claims for failure to warn and negligent design, but rather recognize that failure to warn and negligent design are simply various negligence theories a plaintiff may use to establish liability.

The court in *Lance* further emphasized the flexibility plaintiffs have when bringing negligent products liability claims by clarifying that when a plaintiff advances a negligent design defect claim, the plaintiff may, but is not required to, proffer a reasonable design alternative to demonstrate a manufacturer's negligence. *Id.* at 458 n.37. *See also Soufflas*, 474 F. Supp. 2d at 753 n.13 ("[A]lthough it may be clouded by the frequent muddying of the strict liability waters with concepts of negligence, a products liability action based on negligence does not require proof of a defect."). But once a plaintiff has "premised [his or her] own liability case[] on the

availability of an alternative safer design," he or she "need[s] to prove the[] claim on its own terms in order to succeed." *Lance,* 85 A.3d at 458 n.36. Thus, to establish Zimmer's liability through a negligent design theory, Ms. Batty must show that Zimmer breached a duty of care when designing the NexGen Flex implant and that the resulting design caused Ms. Batty's injury.

Zimmer urges that Ms. Batty should be barred from presenting a theory based on negligent design because she has identified no admissible expert testimony of a defect in the femoral component: Dr. Brown testified that in low flexion, the Flex and the Standard—Plaintiff's proffered alternative safer design—have the same clinical performance, and that if a patient plans to perform high-flexion activities, it is a "no brainer" that the Flex is a better option than the Standard. (Brown Dep. at 84:6–9). Thus, Zimmer urges, Ms. Batty cannot establish negligence in design through a safer alternative design theory. Even if Ms. Batty does present admissible evidence of negligence in the design of the Flex knee, Zimmer continues, the particular design features she identifies could not have caused her injury because Ms. Batty, with one exception, identifies only defects that cause injuries when the implant is used in high flexion—and Zimmer maintains Ms. Batty never achieved high flexion.

Zimmer's reasoning begins with the assertion that Ms. Batty never achieved more than 128 degrees of flexion. (Zimmer Mem. in Supp. of Mot. for Summ. J. [1331], hereinafter "Zimmer MSJ Mem.," 3.) Next, Zimmer urges that below 130 degrees of flexion, the only aspect of the NexGen Flex that differs from the Standard is that the Flex requires an additional two millimeters of bone to be removed from the femur. (*Id*. at 5–6.) Her other theories of design defect—such as the risks of posterior edge loading and the use of the open box design—Zimmer continues, depend on repeated use of the knee at flexion angles above 130 degrees. (*Id.*) Thus, because Ms. Batty cannot, according to Zimmer, identify any evidence that she achieved greater than 130 degrees of flexion, she should be precluded from presenting those theories of negligent design at trial. (*Id*. at 4.) Moreover, Zimmer urges that Plaintiff's expert

testimony regarding the two millimeter bone cut—the only theory that applies in low flexion patients—is inadmissible. (*Id*. at 7–9.) Zimmer concludes that Plaintiff has failed to identify evidence of any design feature in the femoral component that could have caused her injuries and that Zimmer is entitled to judgment as a matter of law.[38]

Plaintiff responds that Ms. Batty did in fact achieve flexion greater than 130 degrees, even though it was not recorded by her physical therapist. In any event, it is undisputed that Ms. Batty achieved between 120 and 128 degrees of flexion, and Plaintiff urges that her theories of design defect apply to patients who achieve flexion in that range. Third, Plaintiff urges that her expert testimony regarding the two millimeter bone cut is admissible. The court agrees with Plaintiff that disputes of fact preclude summary judgment: First, the parties dispute what degree of flexion Ms. Batty actually achieved. Second, Plaintiffs have presented evidence suggesting that the defects based on high-flexion use might emerge in patients who achieve flexion between 120 and 130 degrees. Finally, Plaintiff may establish negligent design through evidence relating to the Standard as a safer alternative design: the court has already

[38] In its reply brief, Zimmer appears to assert, for the first time, that Ms. Batty presents no evidence that she had femoral loosening and she should be prevented from presenting any theory that suggests a defect causes femoral loosening. (Zimmer Partial MSJ Reply Br. [1488] at 1, 6.) Zimmer notes that Ms. Batty's revision surgeon, Dr. Crossett, stated that he did not believe the femoral component on the left leg was loose (Crossett Dep. 151:10–11), and that the interface between the cement and metal on the right femoral component "was interrupted with small oscillating saw and then the small osteotomes had loosened it up circumferentially on both sides." (Dr. Crossett Revision Reports, Ex. 25 to Ronca Decl. [1462-25].) That is, Dr. Crossett could not remove the femoral components as easily as the tibial components. It is well-established that arguments raised for the first time in a reply brief are waived. *Narducci v. Moore,* 572 F.3d 313, 324 (7th Cir. 2009) ("[T]he district court is entitled to find that an argument raised for the first time in a reply brief is forfeited."). In any event, Plaintiff has identified sufficient evidence to create a genuine issue for trial regarding whether Ms. Batty experienced femoral loosening: Ms. Batty's x-rays show evidence of loosening under the flanges of the femoral component, even though the portion on the bottom side of the condyles remained well-fixed. (*See* Pl.'s Resp. to Mot. for Summ. J. [1463], 12; Fetto Dep. at 362:1–18.) As Dr. Fetto explained as part of his medical opinions about Ms. Batty—which Zimmer has not sought to exclude—the radiolucencies were progressing "into some of the distal femoral area. It hadn't completely gone around. So that would be consistent with what Dr. Crossett said at the time of surgery was the need to use instrument[s] to break the final bond between the cement or the prosthesis and the bone." (Fetto Dep. at 362:11–18.)

determined that Plaintiffs may present the testimony of Dr. Brown regarding the two millimeter bone cut that affects the Flex, even in low flexion (*see supra* Section II.A.2), and Dr. Brown's testimony that the Flex is safer than the Standard in high flexion does not defeat Plaintiff's claims of defect.

1. Ms. Batty's Maximum Degree of Flexion

Zimmer maintains that no trier of fact could reasonably conclude Ms. Batty achieved greater than 130 degrees of flexion because her highest recorded degree of flexion was only 128 degrees. (Zimmer's Reply in Supp. of Mot. for Summ. J. [1488], hereinafter "Zimmer MSJ Reply Br.," 2; Zimmer SOF ¶ 42; PT Notes.) Absent a recorded flexion angle greater than 130 degrees, Zimmer insists, a conclusion that Ms. Batty had achieved flexion greater than 130 degrees would be pure speculation. (Zimmer MSJ Reply Br. at 2); *see Collins v. Am. Red Cross,* 715 F.3d 994, 997 (7th Cir. 2013) (court reviewing summary judgment motion "will not draw inferences that are supported by only speculation or conjecture.") (internal quotations omitted). A jury may ultimately agree with Zimmer's reading of the evidence, but the court declines to conclude as a matter of law that the only credible evidence of flexion is a clinically recorded flexion angle. And, Zimmer's position ignores Ms. Batty's evidence (discussed below) supporting an inference that she achieved more than 130 degrees of flexion.

First, the court is unwilling to require Plaintiff to present clinical measurements to prove flexion because Dr. Brown presents several reasons to view these clinical measurements as "only loosely approximate." (Brown Rebuttal Report to Wright, Ex. G to Ronca Decl. [1464-7], 7.) He notes that clinicians use several different approaches to measure range of motion: a passive measurement is taken with the patient lying on his or her back with a relaxed knee while the examiner manually pushes until he or she feels resistance. (*Id.*) An active measurement is obtained while the patient volitionally flexes his or her knee, and an active assisted measurement combines the first two approaches: the patient actively flexes while the examiner

pushes on his or her knee. (*Id.*) In addition to the active versus passive options, clinicians use a variety of mechanisms for measuring the degree of flexion. Some measurements are

> done purely by visual estimation of the investigator. Alternatively, it is sometimes done with a hand-held goniometer, a simple two-armed instrument (usually of clear plastic) with a ruled angular scale, one arm of which is held against the patient's thigh and the other against the patient's shank. Or, most definitively, angular measurement sometimes . . . is done by taking a lateral x-ray, allowing formal measurements of the angulation directly between the femur and tibia bones themselves.

(Brown Rebuttal to Wright at 7.) Each of these approaches can produce a different measurement, suggesting that a single clinical measurement is not definitive evidence. (*Id*.) Dr. Brown opines further that measurements made in a clinical setting are often significantly lower than the flexion angles patients achieve during real-world functional activities. He cites one study that compared x-ray measurements of squatting patients with goniometer measurements of passive knee flexion and found that the goniometer measurements "underestimate actual knee range of motion by an average of 20°." (*Id*.) From this testimony, a jury could reasonably infer that Ms. Batty's clinically documented flexion of 128 degrees suggests she did achieve flexion greater than 130 degrees in her activities of daily living.

Ms. Batty's description of her daily activities after the replacement surgery supports such an inference. After her formal physical therapy ended, Ms. Batty continued to exercise about four times a week, performing roughly 60 squats: 30 using both legs, plus 15 squats on her right leg alone, and 15 on her left leg. (*See* Batty Decl. ¶ 3.) Though Ms. Batty testified that the squats she was performing did not cause her calf and thigh to touch, and in fact "[t]hey haven't touched in years," (Batty Dep. at 196:14), she stated in her declaration that she "believe[s] the amount of bend [she] got doing the squats was more than [she] got in the office with Dr. Klein when he would gently bend [her] knee." (Batty Decl. ¶ 3.) Zimmer seizes on her testimony that she was not "ever able, outside of physical therapy to bend [her] knee more than they bent it in physical therapy" (Batty Dep. at 199:25–200:3), urging that this is dispositive on the question regarding her maximum degree of flexion, but Ms. Batty immediately explained that she did not

actually know whether she bent her knee more outside of therapy because she "did not have someone else measuring it." (*Id*. at 200:4–8, 200:18–24.) This testimony creates a fact question about what degree of flexion Ms. Batty achieved, a question which the court is not permitted to resolve at summary judgment.

By October 2009, Ms. Batty was back at work full-time as a custodian for the U.S. Postal Service, with no physical restrictions. (Pl.'s SAF ¶ 12; Batty Decl. ¶ 4.) Her job responsibilities included maintaining a large flower bed, requiring her to plant more than 200 flowers in the bed—she does not say over what time period—and to pull weeds to preserve the garden's appearance. (Batty Decl. ¶ 4.) Ms. Batty had to kneel and squat to complete this work. (*Id.*) She also climbed ladders and washed baseboards. (*Id.*) Zimmer's brochure for the NexGen Flex itself recognizes that activities like these require high flexion: That brochure states "Many activities of daily living require flexion beyond 120 degrees. Consider climbing stairs (75–140 degrees), sitting in a chair and standing up again (90–130 degrees), or squatting (130–150 degrees.)" (Zimmer Brochure, Ex. B. to Pl.'s MSJ Resp. Mem. [1464-2], Z05607999.) Viewing the evidence in the light most favorable to Ms. Batty, a jury could reasonably conclude that, while squatting, kneeling, and climbing ladders and stairs, at least occasionally, she achieved at least 130 degrees of flexion.

Zimmer replies that it "believes that the measurement taken by a plaintiff's medical providers are the best indicator of whether he or she had high-flexion capability." (Zimmer MSJ Reply Br. at 3.) But the "court may not choose between competing inferences or balance the relative weight of conflicting evidence." *Hansen v. Fincantieri Marine Grp.*, LLC, 763 F.3d 832, 836 (7th Cir. 2014) (internal quotations and alterations omitted). The jury may ultimately agree with Zimmer, but it is for the jury to decide what evidence constitutes the "best indicator" of Ms. Batty's flexion.

2. Plaintiff's Theories Of Defect Apply Between 120 And 130 Degrees of Flexion

If Ms. Batty does present evidence of occasional flexion greater than 120 degrees, Zimmer argues, this would nevertheless be insufficient to support a verdict in her favor. Zimmer also contends that the defects Plaintiff claims occur when the knee is used in "high flexion" do not occur unless a patient achieves 130 degrees of flexion. Zimmer highlights Dr. Brown's opinion that "patients with flex implant versions who do not typically use their implants for high-flexion activities would tend to have clinical performance reasonably consistent with that of patients who have the standard implant versions." (Brown Rep. at 12.) There is ample evidence in the record, however, that conditions that constitute "high flexion," and that may cause loosening, can occur in flexion ranges between 120 and 130 degrees.

First, Dr. Brown's testimony suggests that the definition of "high flexion" will vary from person to person. Dr. Brown did define "high-flexion" in his report as approximately 130 degrees (*Id*. at 11, n.5), but later clarified that bioengineering "often necessitates substantial levels of approximation . . . because living systems are inherently variable . . . [s]o, oftentimes, when speaking quantitatively in the field of bioengineering, it is therefore more appropriate to speak in approximate terms." (Brown Rep. at 25, n.10.) In his deposition, Dr. Brown resisted a bright-line definition of "high-flexion," explaining that "I kind of like to think in terms of a zone that kicks in around 120." (Brown Dep. at 228:11–13; *see also id.* at 13:1–3.) When asked if he would consider 121 degrees high flexion, he explained that "it could be individual-specific . . . so I think that one needs to keep in mind a range."[39] (Brown Dep. at 19:4–13.) Zimmer has not established that high flexion is, as a matter of law, only flexion above 130 degrees.

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[39] Dr. Brown explains that whether a patient achieves high flexion depends on the interior dynamics of the patient's knee, specifically on when "the center of contact is at the far posterior extreme of the tibial plateau . . . [a]nd . . . a very few millimeters anteriorly of that." (Brown Dep. at 14:10–18.) Zimmer urges that, under this definition, to survive summary judgment, Ms. Batty must present "evidence that would permit a jury to find that the interior dynamics of the plaintiff's knee and the movement of the center of contact meets these (continued . . .)

Next, Dr. Brown notes in his report that the key determining factor for loosening is whether patients engage "in demanding situations of high flexion usage." (Brown Rep. at 12) (emphasis omitted.) He also highlights a study by *Cho et al*., which found that "radiolucent lines were much more likely to develop in patients who could fully squat, versus in patients who could not fully squat." (*Id*. at 11 (citing Cho et al, *Three- to six-year follow-up results after high-flexion total knee arthroplasty: can we allow passive deep knee bending*? 19 Knee Surg. Sports Traumatol. Arthosc. 899 (2011)).) *Cho et al*. recommended that squatting and kneeling be prohibited in patients with the NexGen LPS-Flex implants. (*Id.* at 12.) Reading this evidence in Plaintiff's favor, a jury could conclude that a patient who engaged in "high flexion activities," such as kneeling and squatting, would be more likely to experience loosening, regardless of the specific measurement of flexion recorded in his or her medical records.

Third, Plaintiff has presented evidence that suggests the risks of femoral loosening may increase well before a patient reaches 130 degrees of flexion. For example, Dr. Brown notes a report in one of Zimmer's internal records that during cadaveric testing of the CR-Flex design, in the first two specimens evaluated, the femoral component "was observed to pull loose from the bony femur beyond 90° of flexion, and to be separated by a gap of 6 mm at 130° of flexion." (*Id.* at 14 n.7.) Dr. Brown also notes the FEA analysis conducted by *Zelle*, which found that "during full squatting maneuvers, the failure strength of the fixation interface [between the femoral component and the femur] was not seriously challenged for flexion angles below about 120°. However, for flexion angles between 120° and 145°, interfacial stresses exceeded interface failure strength beneath portions of the femoral component's anterior flange." (Brown Rep. at

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conditions." (Zimmer MSJ Reply Br. at 3.) The summary judgment standard is not so demanding. Summary judgment is proper "[o]nly if the court can say, on [a] sympathetic reading of the record, that no finder of fact could reasonably rule in" Ms. Batty's favor. *Hotel 71 Mezz Lender LLC v. Nat'l Ret. Fund*, 778 F.3d 593, 603 (7th Cir. 2015). Thus, Ms. Batty need not present specific measurements of her knee. Rather, to proceed to trial she need only present evidence from which a reasonably jury could infer that she engaged in high flexion activities. As explained in the text, she has met that burden.

28.) Dr. Brown acknowledges that *Zelle*'s model did not rely on a Zimmer implant design, but explained that "the computational result is strikingly consistent with the failure modalities seen clinically for Zimmer NexGen-Flex implants." (Brown Rep. at 28.)

Similarly, Dr. Brown cites evidence that factors causing tibial loosening can occur at flexion ranges beginning around 120 degrees. Zimmer measured the contact area between the femoral and tibial components at 0, 10, 45, 90, 130, and 155 degrees. (Brown Rep. at 45–46.) The testing revealed that at 130 degrees, the Flex had a smaller contact area, 126 mm^2, than the Standard, which had 149 mm^2. (Brown Rep. at 46.) While there is no testing or data for the contact area in the 120–130 degree range, extrapolation from the test results suggests that between roughly 100 and 135 degrees of flexion, the Flex design has smaller contact area than the Standard. (*See* Zimmer Tech. Mem., Ex. E to Becker Aff. [1460-5], Z007131; Zimmer Design Rationale, Ex. G to Becker Aff. [1460-7], Z000020.) As Dr. Brown explained, the concentrated pressures that come from smaller contact areas increase the risk of loosening and micromotion of the tibial component. (Brown Rep. at 47–48.) In sum, a reasonable jury could conclude that, even if Ms. Batty never achieved 130 degrees of flexion, the design of her knee implants caused aseptic loosening of her components due to the interfacial stresses on the femoral component and the smaller contact area between the femoral and tibial components that occur between 120 and 130 degrees

3. Safer Alternative Design

Zimmer also urges the court to grant summary judgment on Plaintiff's design defect claims because Plaintiff has failed to present evidence of a safer alternative design. According to Zimmer, "Plaintiffs' experts agree that the Flex products are not harmful to patients who do not achieve high flexion, and Dr. Brown makes clear that it is a 'no brainer' that the Flex products are even safer for those who do." (Mult. Grounds Mem. at 7.) Zimmer maintains that the two devices are equally safe at low degrees of flexion based on Dr. Brown's testimony that, other than the two millimeter bone cut, "there's every reason to suspect similar performance" at

low flexion. (Brown Dep. at 67:7–12.) Zimmer reasons that "logically, if the NexGen Flex performs as well as the NexGen standard, the NexGen Flex . . . is not defective." (Zimmer MSJ Mem. at 6.) The court has already concluded, however, that Dr. Brown may present testimony regarding the additional risks created by the two millimeter bone cut, which affects the Flex in low-flexion, but not the Standard. Thus, Plaintiff has established a genuine issue for trial regarding whether the NexGen Flex performs as well as the Standard in low-degrees of flexion, in light of the additional two millimeters of bone that must be removed.

Zimmer also asserts that Plaintiff's effort to prove a defect through a safer alternative design fails because the Flex is safer than the Standard in high flexion. (Zimmer MSJ on Multiple Grounds Mem. at 7.) Dr. Brown testified that "if you know that you're going to go beyond 130, would you rather have it happen with a NexGen-Flex than a NexGen Standard? I think that's a no-brainer. You want the Flex." (Brown Dep. at 84:6–9.) Zimmer urges that this statement proves that Ms. Batty "cannot satisfy a central element of her negligent design claim under Pennsylvania law." (Mult. Grounds Reply at 11.) The court disagrees. Dr. Brown's testimony does not undermine Plaintiff's theory that the Flex, while potentially safer at 155 degrees of flexion than the Standard, poses more risks than the Standard when used at flexion angles between 120 and 130 degrees. Plaintiff also alleges that Zimmer rushed to market the high-flexion designs without sufficient testing, and should not have advised that high-flexion activities were safe with an under-tested product. The critical difference between the Flex and the Standard, with respect to this theory, is that the Standard was not intended for high-flexion use because it was not considered safe at flexion angles above 130 degrees. (*See* Brown Rep. at 45.) Dr. Brown emphasizes this point in his report, explaining that to evaluate the safety of the Flex, Zimmer should have compared how each device performed at its maximum intended use, by comparing the performance of the Flex at 155 degrees to the Standard at 130. Zimmer warned that the Standard was not safe for use beyond 130 degrees of flexion. Dr. Brown asserts that it was not reasonable to evaluate the safety of the Flex by comparing it to how the

Standard performed at flexion angles that Zimmer knew to be unsafe. (Brown Rep. at 46.) That is, Plaintiff's theory is that the combination of Zimmer's negligent product design, inadequate testing, and promises that the product was safe for high-flexion use posed an unreasonable risk of harm to patients who engaged in high flexion activities, including Ms. Batty. Nothing about Dr. Brown's statement that the Flex is safer at 155 degrees than the Standard defeats that theory.

V. Loss of Consortium

Zimmer argues that Plaintiff's husband, Thomas Batty, is precluded from bringing a loss of consortium claim, because Plaintiff herself has no viable cause of action remaining. (Mult. Grounds Mem. at 19.) As discussed above, Plaintiff does have viable claims remaining, and therefore the loss of consortium claim necessarily survives summary judgment.

CONCLUSION

For the reasons discussed above, Zimmer's motion to exclude Dr. Brown's testimony [1298] is denied. Zimmer's motion to exclude Dr. Joseph Fetto's [1300] testimony is denied with respect to Dr. Fetto's rebuttal report to Dr. D'Lima, but is otherwise granted. Because the court will admit Dr. Brown's testimony, Zimmer's motion to exclude all testimony relating to tibial loosening [1309] is necessarily denied. Zimmer's motion for summary judgment and partial summary judgment [1317] is also denied, as outstanding issues of material fact remain as to whether Ms. Batty achieved high flexion, and Dr. Brown's testimony on the two millimeter bone cut is sufficient, on its own, to generate a fact issue as to whether Zimmer acted negligently in its conduct related to the NexGen Flex design.

Finally, Zimmer's motion for summary judgment on multiple grounds [1306] is granted in part and denied in part. It is granted as to Plaintiff's claim premised on strict liability, as the Supreme Court of Pennsylvania, if presented with the issue, would not recognize such a claim. That motion is denied, however, with respect to Plaintiff's remaining negligent design theories based on femoral and tibial loosening, as well as on the loss of consortium claim brought by Ms.

Batty's husband. Other remaining negligent design theories that could support a finding of liability and that are not specifically rejected in this opinion remain viable. That being said, the court reserves judgment on the failure to warn theory, as the question of whether Plaintiff may present evidence associated with this theory is linked to Dr. Samaras' and Dr. Klein's *Daubert* motions, which are still pending. The court also declines to rule on the punitive damages claim at this time.

In addition to the issues mentioned above that the court has refrained from resolving (including failure to warn, and punitive damages), the following *Daubert* motions remain pending:

1. Plaintiff's Motion to Strike Testimony of Dr. Darryl D'Lima [1311];
2. Plaintiff's Motion to Exclude Testimony of Dr. Timothy A. Ulatowski [1327];
3. Plaintiff's Motion to Exclude Testimony of Dr. Stuart Goodman [1333];
4. Plaintiff's Motion to Exclude Testimony of Dr. Michael Vitale [1337];
5. Plaintiff's Motion to Exclude Testimony of Dr. Timothy Wright [1405];
6. Defendants' Motion to Exclude Testimony of Dr. Alan Klein [1297]; and
7. Defendants' Motion to Exclude Testimony of Dr. George Samaras [1304].

ENTER:

Dated: June 12, 2015

REBECCA R. PALLMEYER
United States District Judge